

**An Investigation Into  
The Ethical and Legal Aspects of  
Living Donor Organ Transplantation.**

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A thesis submitted in partial fulfilment of the requirements of  
De Montfort University for the Degree of Doctor of Philosophy  
December 1997.

De Montfort University in collaboration with the  
EUROTOLD project.

## Abstract.

Within conventional medicine, transplantation is widely viewed as the 'gold standard' in the treatment of organ disease. However, there is a chronic shortage in the availability of several types of organ, including kidneys. Reducing the shortfall, and indeed removing it, is acknowledged as the major aim in transplantation today. However, in most transplanting jurisdictions, the uncontroversial methods of increasing supply have largely already been put into practice. At the same time the number of people diagnosed with organ disease is increasing - rapidly so in the case of kidneys.

It is uncertain if, or when, xenotransplantation or artificial organs will supply large numbers of organs effectively. The global choice *now* is relatively simple; adopt controversial methods of increasing cadaveric supply (such as elective ventilation and/or use of non-heart beating donors) and/or increase living donation OR endure continued damaging effects of shortage (lower quality of life on dialysis and death where dialysis is not available). Increases in living donation alone may be capable of delivering the additional numbers of organs to remove the organ shortage. However, use of living organ donation raises novel and very significant legal and ethical issues. These issues arise primarily from the inevitable fact of donation: that it causes a degree of harm, and risk of further harm, to the donor. In addition, there is the relatively unexplored question of what the unique relationship of donor and recipient means for both legally and ethically. In the context of other options, an in-depth ethical analysis of LDT is required in order to establish the parameters within which its use can be justified. This thesis, along with EUROTOLD's Final Report, breaks new ground by considering all major ethical issues within a single document.

A regulatory framework for LDT is the main method of stipulating the ethical parameters within which it may acceptably take place. It also provides the foundation for defining the relevant autonomy at each level of the LDT process; the role and content of law, codes of practice, protocols and the ambit of individual professional and participant discretion. A number of reviews of transplant law have been produced including Fuenzalida-Puelma's survey of legislation pertaining to 16 South American countries<sup>1</sup> and the World Health Organization's recent book 'Legislative Responses to Organ Transplantation.'<sup>2</sup> While the latter was limited to setting out, without analysis, the organisational and statutory regulation of transplantation activity the former was limited in geographical area. This prompted Sev

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<sup>1</sup>Organ Transplantation: The Latin American Legislative Response. In S.S.Connor and Fuenzalida-Puelma (eds.) Bioethics: Issues and Perspectives, *Pan American Health Organization*, 1990, 67-86.

<sup>2</sup>*Martinus Nijhoff*, 1994.



Fluss in a recent review to suggest the possibility of an up-to-date global survey.<sup>3</sup> This thesis produces the first such survey - critically with a landmark analysis of core ethico-legal issues in LDT (disclosure, informedness, voluntariness and capacity in relation to consent and regulation of financial exchange in LDT<sup>4</sup>).

Ethico-legal issues in LDT interact with the practical context. The thesis examines current studies of attitudes, practice and experience of participants and professionals in LDT and builds on them through a programme of empirical investigation (Transplant Centre Questionnaire, a Professional Attitudes Questionnaire and Donor and Recipient Questionnaires) unique in content and scope of jurisdictions covered.<sup>5</sup>

**Authors Note:** the oral defence of this thesis was successfully completed in May 1998, submission to the De Montfort University library in June 1998. Readers should be aware of new developments since write up of the PhD in 1997. These include:

- publication of the Convention on Human Rights and Biomedicine (Council of Europe);
- ongoing development of transplant legislation (e.g. in Germany) - abstracts of new legislation tend to appear in the WHO's International Digest of Health Legislation.;
- more current statistics for transplantation will now be available from the Council of Europe and national (and cross national transplant bodies). The broad picture of spiralling demand for kidneys continues; *and*
- the setting up of UKXIRA a public body regulating xenotransplantation issues in the UK. (The grave danger, from this authors point of view, is that clinical trials of xenotransplantation may soon go ahead despite lack of resolution of either the ethical and public safety issues or a public debate and public consensus. Some of these issues will

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<sup>3</sup>Trade in Human Organs: National and International Responses in Transplantation in the European Union: Management of Difficulties and Health Risks Linked to Donors, (ed. Yvon Englert), *Martinus Nijhoff*, 1995 at 75.

<sup>4</sup>It involves fundamental analysis of world-wide statutory provisions and some broad approaches of judge made law. This original global analysis was made in conjunction with the development of LEGISEARCH, EUROTOLD's database of European living donor transplant law. LEGISEARCH was developed by David Price and I with the assistance of several EUROTOLD's legal contacts who have written papers on living donor transplant law provisions and in some cases responded to EUROTOLD's legal questionnaire (see Appendix 3). Legisearch is available on the internet at <http://maths.ac.uk:2080/MedStats/Eurotold>.

<sup>5</sup>There was a study of attitudes amongst 148 European Transplant Centres (see Editorial, *Lancet*, 1982, ii, 696) but this was back in the early 1980's and covered a much narrower range of countries than the EUROTOLD investigation. The EUROTOLD project has also developed a Donor Health Registry with a donor health form designed to elicit information about tests conducted on donors and the medical consequences of donation. Data return is still in it's infancy and consequently this work is not significantly discussed. The central intention of the form and Registry is to elicit a large body of data on the long term health consequences of donation. This will have important consequences in helping to assess any long term risks of donating a kidney, integrating this assessment into information provided to potential living donors and recipients and whether the amount of risk is ethically acceptable and within legally permissible limits.

note doubt get a thorough and thoughtful airing in the forthcoming book being published on transplantation by David Price, one of the two supervisors to this PhD.

EUROTOLD continues to exist as a project; collating information from across Europe for it's donor health registry and in the form of many of it's members continuing to write extensively on ethical, legal and other aspects of living donor organ transplantation.



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## **Glossary of Main Abbreviations.**

LDT - living donor organ transplantation  
 CDT - cadaveric organ transplantation  
 ULTRA - Unrelated Live Transplants Regulatory Authority  
 HOTA - Human Organ Transplants Act 1989  
 NHBD - non heart beating donor  
 EV - elective ventilation  
 EUROTOLD - European multidisciplinary study of LDT

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## **Background to the Investigation and Acknowledgements.**

In 1987 a paper was written on living donor kidney transplant attitudes and practice amongst transplant centres in the UK. and Eire by members of the Leicester transplant centre.<sup>1</sup> From this early beginning an ongoing study, focusing on ethical and legal aspects of living donor transplantation in Europe, was initiated by Leicester University Department of Surgery, De Montfort University School of Law and Newcastle University Department of Statistics. In February 1991 I joined the existing De Montfort team of David Price and Ronnie Mackay for the purposes of research collaboration and to commence a Ph.D. on this subject. Early work focused on interviews with clinicians, lawyers and ethicists with an interest in the transplant field and developing and piloting an interview strategy with living donors and recipients.

In 1993 the project adopted the title EUROTOLD an acronym for a 'Multidisciplinary European Study of Transplantation of Living Donors.' EUROTOLD contracted with the European Community (Ref : BMH1-CT92-1841) to undertake research into the ethical and legal aspects of living organ donation extensively and systematically in Western Europe. The project had a number of clinical participants from transplant centres across Europe as well as other experts from a variety of other disciplines including law, ethics, psychology and economics. In 1994 - 1995 a further 6 countries from Eastern and Central sub-contracted with the European Community for devolved funding under the PECO programme to collaborate in the project with EUROTOLD acting as a co-ordinator. These countries were Estonia, Albania, Slovenia, Poland, Hungary and Romania.

As a member of the EUROTOLD project management group I was honoured to be extensively involved in project activities. The particular focus of my work was:

- attending a number of international workshops meetings and conferences
- liaising with leading researchers and practitioners in this area
- interviewing living organ donors and recipients
- helping to develop, administer and analyse professional questionnaires

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<sup>1</sup>P.K.Donnelly et al., Transplants From Living Donors in the United Kingdom and Ireland: A Centre Survey, *BMJ*, 1989, 298, 490-493.

- being an ambassador for the project in Europe

This work provided a solid foundation for the development of the PhD thesis. I would like to thank all those who participated in the project and other members of the project management group for their collaboration and dialogue. My special thanks to David Price and Ronnie Mackay who provided invaluable advice and assistance as mentors and experts in medico-legal issues.



## Historical Context: 5 Key Phases in Organ Transplantation

Transplantation has gone through several phases:

- *Firstly*, very basic attempts at xenografting.<sup>2</sup> Unger's conclusion from the limited graft survival of such attempts was that there was a biochemical barrier to transplantation.<sup>3</sup>
- Not surprisingly, the *second* phase was one of a lull in activity from around 1910 to the late 1940's. The exceptions to this were the development of corneal transplantation which had become routine by the 1940's<sup>4</sup> and the notable event of the first allograft (human-human) transplant in Ukraine in 1933 which did not have significant graft survival.<sup>5</sup>
- The *third* significant phase began in 1947 when the first long term level of allograft survival was achieved from a living donor transplant in Boston, U.S.A. which utilised identical twins.<sup>6</sup> Here, by accident, the biochemical barrier had been side-stepped. As twins the donor-recipient pair had matched body materials.<sup>7</sup> The first non-identical twin donor-recipient pair were operated on a few years later, again with successful graft survival.<sup>8</sup> Twin transplantation paved the way for the understanding that the biochemical barrier was the body's natural immunological response to foreign material.
- The knowledge of immunological response founded a *fourth* phase of primitive immune suppression; this began in 1959 with the use of sub-lethal doses of whole body irradiation!<sup>9</sup>
- The *fifth* phase which exists today was founded on developed methods of immune response suppression. The key development was the use of a drug called cyclosporin from 1983. Cyclosporine could be used on it's own or in combination with other immunosuppressants with sufficient success to revolutionise organ procurement. Now lesser matched genetic materials could be utilised with increasing success. An era of extensive use of cadaveric transplantation began in earnest, especially in Europe.

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<sup>2</sup>Ullmann has claimed the earliest attempt with kidneys in 1902 (*Ann.Surg*, 1914, 60, 195-219). Jaboulay has the first two recorded attempts (*Lyon M/ed*, 1906, 107, 575-577).

<sup>3</sup>*Berl.Klin.Wschr*, 1909, 1, 1057-60. Unger's own 2 attempts had failed to produce significant graft survival. Unger's insight was proved correct by the later scientific understanding of the natural human immunological response to reject non-compatible materials from the body.

<sup>4</sup>Anon., *New Scientist*, 1989, 25. Corneal transplantation had begun in 1905.

<sup>5</sup>D.Hamilton, A History of Transplantation in P.J.Morris (ed.) *Kidney Transplantation*, 1988 at p4.

<sup>6</sup>*Ibid* at p4.

<sup>7</sup>1954, Boston. See J.Murray et al., Successful Homotransplantation Between Identical Twins, *Surg Forum*, 1955, 6, 432.

<sup>8</sup>J.P.Merrill et al., Successful Homotransplantation of the Kidney Between Non-Identical Twins. *N.Engl.J.Med*, 1960, 262, 1251.

<sup>9</sup>See D.Hamilton, A History of Transplantation in P.J.Morris (ed.) *Kidney Transplantation*, 1988 at p4.

## **Chapter 1: Introduction.**

The purpose of this introductory chapter is to identify the following: the main purposes of and for the investigation; methodologies utilised (in conducting and writing up the thesis) to achieve the major aims; the ethics of the investigation; *and* limits of the investigation.

### **1.1. The Main Purposes of and for the Investigation.**

In some marginal or experimental areas the results of transplantation may not be acceptable either in their own right or in comparison to dialysis.<sup>1</sup> However, it is uncontentious that transplantation is the 'gold standard' in terms of quality of life for conventional treatment of most forms of organ disease. In addition, with regard to treatment for End Stage renal Failure (ESRF), it has been stated that,

"(t)ransplant is by far the cheaper option, especially when one considers that the vast majority of recipients are restored to full time work, with consequent savings in pensions or benefits to the remaining family members."<sup>2</sup>

Data from the late 1980's gives an approximate cost for kidney transplantation of £10,000 with about £3,000 per annum thereafter for follow-up care. This compares with roughly £18,000 for hospital haemodialysis, £13,000 for CAPD and £11,000 for

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<sup>1</sup>There are several examples in the history of transplantation where its use was questionable within almost any framework of ethics. For instance after Dempster had discovered that radiation would delay rejection by weakening immunological response (W.J.Dempster, *Brit J Surg*, 1953, 40, 447-465). Attempts at promoting extended graft survival bordered on the insane in some instances including the attempt to achieve a modest gain by the administration of sub-lethal doses of whole body irradiation. Even the modern regime dominated by cyclosporin has problems related to the inherent contradiction of suppressing a person's immunological system and attempting to maintain health at the same time. For instance, the New York Task Force has indicated that side effects of cyclosporine can include, "tremors, convulsions, swelling and inflammation of the gums, abnormal growth of body hair and increased incidence of lymphoma and Kasposi's sarcoma." Hypertension, hepatitis and cancer are risks and the kidneys can be toxified by use. It is just as well in one sense that transplantations last on average only about a decade because long term exposure to this drug may frequently have very serious side effects. *Task Force*, 1988, 20.

<sup>2</sup>Organ Transplantation, Richard West, *Office of Health Economics*, 1991, 25. For a further economic analysis see De Charro, papers presented at Warsaw and Rotterdam (transcripts from EUROTOLD).



home haemodialysis per annum.<sup>3</sup> With grafts on average lasting over a decade this means transplantation is less than half the price of the cheapest form of dialysis.<sup>4</sup> The economic benefits of transplantation when utilised in preference to dialysis are also apparent when it is LDT specifically that is used. De Charro<sup>5</sup> and Spital<sup>6</sup> have produced cost benefit analyses that specifically highlight reduced costs and increased patient quality of life (this has led some clinicians to conclude they would conduct LDT's even if the result of CDT were as good<sup>7</sup>).

Economic and quality of life issues are now being combined in QALY's (quality adjusted life years). In 1990, Professor Alan Maynard 'guestimated' the quality adjusted life year of a kidney transplant at £4,710 compared with home dialysis at £17,260 and hospital dialysis at £21,970.<sup>8</sup> Use of QALY's has raised issues,<sup>9</sup> but not in transplantation because quality of life and economic factors point in the same direction. Consequently the clear aim should be to maximise transplantation (within sensible limits) with dialysis being confined to a complementary, supportive role. The fact that dialysis has gone way beyond this role is partly a consequence of their having been an insufficient supply of organs (particularly renal organs - see graphs 1-3 pages 52-54)<sup>10</sup> to meet demand. With the technical barriers to effective transplantation having fallen away, the 1980's and 1990's saw the ironic position of this insufficiency being the major issue to resolve in transplantation. The degree of insufficiency has meant long waiting times for prospective CDT patients are typical, with consequent deleterious economic and quality of life consequences even if the patient is on dialysis. The position is worsening over time with the increasing gap

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<sup>3</sup>Ibid at 26. Similar data also exist for Spain see *Trans Proc*, 1991, 23(5), 2574.

<sup>4</sup>1995 figures indicate that transplantation costs less than a third. *The Sunday Times*, 1995, 30 July.

<sup>5</sup>Rotterdam Symposium (transcript held at the EUROTOLD project).

<sup>6</sup>R.Spital, M.Spital and A.Spital, The Donor's Decision in Renal Transplantation: A Cost Benefit Analysis, *Am J Kid Dis*, 1987, IX(5 May), 396-403. A cost benefit analysis of transplantation was developed by Spital as a rough model for clinicians to allow living donation where the analysis was positive. The model was designed partly to encourage more discussion and openness with patients about the possible options and is generally supportive of living donation.

<sup>7</sup>For instance Weiland et al., state that: "We would continue to use living-related donors even if the results of cadaveric and LRD transplantation were equivalent, otherwise, ESRD patients would be denied transplantation because of the shortage of cadaver kidneys." (Information on 628 Living-Related Kidney Donors at Single Institution With Long Term Follow-Up in 472 Cases, *Trans Proc*, 1984, 16, 5-7.).

<sup>8</sup>Ibid at 26 these figures are based on 1990 prices using the Rosser Valuation Matrix for analysis.

<sup>9</sup>J.Harris, QALYfying the Value of Life, *J of Med Eth*, 1987, 13, 117-123.

<sup>10</sup>The supply-demand gap is examined in more detail in chapter 2.



between supply and demand (due partly to increased incidence, or at least diagnosis of organ disease.

Solutions to the organ shortage are needed with some urgency. Ethically 'neutral' approaches to improving cadaveric supply must be the first recourse. Some supply improvements could be brought about by approaches like creating a proper infrastructure for CDT in countries where such an infrastructure does not exist or is deficient,<sup>11</sup> facilitating changes in attitudes toward CDT *and* clinical and organisational improvements on the success rate of current organs harvested.<sup>12</sup> However, such methods will probably not deliver anything like the increases required for supply to start matching demand.

Of other options for increased supply, xenotransplantation (with 'mutagenic' pigs and/or higher primates) has already been conducted in experimental fashion between animal species.<sup>13</sup> However, it must be ruled out as a source of human organs in the short and medium term because of major public health concerns,<sup>14</sup> unresolved and divisive ethical issues, lack of public discussion of the issues and questions of cultural acceptability. An unquantifiable, but probably large, number of organs will have to be procured through LDT and/or use of 'ethically marginal' methods of cadaveric procurement. The acceptability of these options must be examined in the light of the alternatives (continued death through lack of dialysis and transplantation and/or lower quality of life on dialysis) as well as in isolation. All of these options

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<sup>11</sup>This applies to most third world and some second world countries many of which even if they conduct a limited amount of transplantation are hampered through not being able to afford comprehensive dialysis facilities. In some countries such as India this has resulted in the almost exclusive use of living donor transplant where the recipients unfulfilled need for dialysis (and possible resulting death) can be averted by the use of living donation before dialysis becomes essential. In several European countries lack of complete dialysis facilities increases the need for LDT (e.g. Poland). In Albania, neither dialysis or transplantation exist at this point.

<sup>12</sup>These are discussed further in chapter 2.

<sup>13</sup>With regard to kidneys studies have suggested that non-human primate kidneys could function normally in a human and sustain life for as long as 9 months (see e.g. D.K.C.Cooper et al. (eds.), *Xenotransplantation: The Transplantation of Organs Between Species*, Springer Verlag, 1991. For a favourable assessment of the ethical issues relating to xenotransplantation see A.L.Caplan, *Is Xenografting Wrong?*, *Trans Proc*, 1992, 24(2), 722-727. For an animal rights perspective on the legal and ethical issues contact Sara Fovargue, Department of Law, University of Newcastle. Particular concerns have long been raised about the use of higher primates (see e.g. K.Reemstra, *Ethical problems With Artificial and Transplanted Organs: An Approach to Experiential Ethics*. In E.F.Torrey (ed.), *Ethical Issues in Medicine*, Little Brown, 1968).

<sup>14</sup>E.g. danger of cross species transmission of mammalian viruses.



have flaws. The core problem with LDT use is that it breaches the '*primum non-nocere*' principle through the detriment it causes donors.<sup>15</sup> Hence, use of LDT is relative; in an era when average CDT results are nearly as good as average LDT results, the use of LDT would be confined to exceptional cases<sup>16</sup> were there a sufficiency of cadaveric organs to meet the demand for them. Elective ventilation, use of non-heart beating donors and systems of presumed consent are marginal methods of cadaveric procurement that could deliver large numbers of organs but raise large ethical issues including those surrounding the violation of consent.

This research is taking place in a critical context of the weight of opinion moving towards the view that LDT is the best option for dealing with shortage that cannot be addressed through 'ethically neutral' CDT procurement methods. After a methodical world-wide analysis of procurement problems and their potential solutions the recent King's Fund Institute Report entitled: 'A Question of Give and Take: Improving the Supply of Organs for Transplantation' recommended,

"increased use of genetically related live donors if backed by new Department of Health Guidance."<sup>17</sup>

Shortly after this The 1995 Report of the British Transplant Society Working Party on Organ Donation<sup>18</sup> specifically reflected on the organ shortage in the UK recommended a package of measures including enhanced use of living donation within certain constraints,

"..renal units should be encouraged to perform more live donor transplants but with the strict proviso that any increase is not at the expense of a reduction in the strict selection criteria as far as donors are concerned. An increase in the number of live

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<sup>15</sup>The Principle of First do no harm - see H.Nys, Desirable Characteristics of Living Donation Transplant Legislation, in Living Donation in the Nineties: European Medico-Legal Perspectives, (ed D.Price and H.Akveld), EUROTOLD, 1996, 117-127.

<sup>16</sup>See for instance Eire which only does HLA identical matches as a deliberate change of policy when the waiting list was reduced to low levels. Some countries despite significant waiting times for kidney transplantation have very little living donation partly because of a high rate of cadaveric transplantation per million population - see Spain (see p64), Portugal (see p63) and Austria (see p57), for example.

<sup>17</sup>Ibid.

<sup>18</sup>Available from the BTS.



donor transplants will require a more active approach to the families of prospective recipients and this is required to be done with considerable care within nationally agreed guidelines and with reference to legal requirements."<sup>19</sup>

The 1995 Nuffield Council on Bioethics Report entitled, *Human Tissue, Ethical and Legal Issues* also concludes that there is a need to undertake more living donation.<sup>20</sup>

However, the cautiousness of procurement recommendations in these reports tackles only the periphery of the core issue of how a massive and rapidly spiralling gap between supply and demand is to be addressed. LDT is likely to be the central solution. It can clearly deliver the required increases. Currently, in virtually all transplant centres and countries, LDT contributes only a small percentage to the overall supply of organs (e.g. in most major transplant countries less than 10% of the volume of kidney transplants - see graphs 34-36 at pages 85-87). It can be projected that increasing LDT use to the point of it supplying between a quarter<sup>21</sup> and a half of the total kidney organs<sup>22</sup> used<sup>23</sup> would result in demand being met in most major transplanting countries and organ distribution areas.<sup>24</sup>

Investigating LDT as a major provider of organs raises the stakes on finding a crystal clear resolution of core LDT ethical issues and the embodiment of these within a transparent regulatory framework. Legal and ethical issues are also very much a rationale for the research in their own right. The *general* legality of organ LDT is nowadays<sup>25</sup> well assured under general legal principles and in many jurisdictions, through explicit or implicit statutory authorisation. Nevertheless, LDT is a very important area for medical ethics and law. It raises novel ethical and legal issues and

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<sup>19</sup>Ibid at p34.

<sup>20</sup>Nuffield Council on Bioethics, 28 Bedford Square, London WC1B 3EG.

<sup>21</sup>E.g. USA, Denmark, Sweden, Norway (see graphs 33 and 34).

<sup>22</sup>This is so in Norway in some years (see graph 34).

<sup>23</sup>Some countries with lower transplant rates like Turkey, Japan and India almost exclusively rely on living donors, whilst Greece used to. In these countries it is low use of cadaveric transplantation that is the major obstacle to sufficiency. These countries provide examples of specific financial or religious / public attitude barriers to setting up an extensive cadaveric programme.

<sup>24</sup>See projection graphs 4-14 and 38-39 at pages 55-65 and 89-90 respectively

<sup>25</sup>Historically the legality of organ LDT was questioned based on it involving risks and consequences to the donor without direct benefits and the argument that it constituted serious bodily harm falling outside the limits of what can be legally consented to. See for instance discussion of legality in the UK before the passing of HOTA in Bar Council Report of Organ Transplants, *BMJ*, 1971 (September), 716.



unusual variations to those raised in medical treatment generally. The uniqueness of LDT stems partly from the fact that neither the prospective donor *or* the prospective recipient is like a 'regular patient' - indeed the prospective donor is not a patient at all. A 'regular patient' *may* need to examine impact on family and/or friends as well as him/herself in reaching a rational decision about treatment. A prospective donor and recipient *may* need to do likewise but the difference is that the prospective donor and recipient *must* consider impact on each other to make a rational decision. The need to make a decision collectively as well as individually binds donor and recipient uniquely together. Adding to the novelty of the situation is the fact that the prospective procedure is physiologically non-therapeutic for the prospective donor - not undertaken for his or her benefit in the ordinary sense, although psychological benefit may vicariously accrue to donors through undertaking the act 'altruistically' and/or through seeing the recipient become more healthy through receiving the organ.

The application of ethical principles and philosophies is complex, multi-faceted and unusual in LDT. The most established philosophical theories used in medical ethics are deontological theory and consequentialism.<sup>26</sup> While deontological theory insists that persons have intrinsic moral worth and should not be treated as means to the ends of other persons, consequentialism attempts to judge the rightness or 'wrongness' of an action by the consequences that flow from it. In its extreme form this would allow people to be treated as ends for overall utility without reference to their rights as people. However Mill's modified utilitarianism somewhat integrates the two theories by stressing that respect for people as ends in themselves is essential for maximising overall utility.<sup>27</sup> Extreme consequentialism is unacceptable because the individual is left continually vulnerable as noted by Gillon:

"..if overall maximisation of welfare is the supreme moral objective the individual seems to be in permanent jeopardy before the overriding interests of society."<sup>28</sup>

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<sup>26</sup>There is also totality theory which stems from Catholic moral theology and emphasises in the context of LDT that any body severability affects the physical completeness of a human being and is therefore an unacceptable interference with nature and God's order - other objections to LDT as a whole are outlined in chapter 1.

<sup>27</sup>J.S.Mill emphasises this approach - see R.Gillon, *Philosophical Medical Ethics*, 1986.

<sup>28</sup>R.Gillon, *Philosophical Medical Ethics*, 1986 at p25.



The result can also be state totalitarianism; where atrocities and abuses of power are justified in the name of social good. Medical treatment has historically included decisions based on extreme consequentialism - sterilisation on eugenics grounds is one example that has occurred in a number of countries within living memory with the backing of law. Today the importance of placing utility within the overriding context of respect for rights is widely accepted. Respect for the rights of prospective donors has been recognised as central to LDT by The Transplantation Society which, in The Statement of the Committee on Morals and Ethics, has declared that,

"in all instances the risk to the donor and consideration of the donor's mental and physical health must be a primary consideration, and the benefit to the recipient secondary."<sup>29</sup>

One of the key things to avoid in practice is members of the public being vulnerable to attempts to extract their organs without consent; a violation over and above that normally experienced where a medical procedure is not consented to because the act of donation is not for the donors benefit. In general this is easy to legislate against but what if there is a donor who is incapable of giving a legally valid consent? Should they be allowed to donate with their agreement? Be mandated to donate without their agreement? The prospect of such donation raises the issue of whether donation can reasonably be declared as in a donors best interests and if it can how can it be ensured that best interests rather than utilitarianism is the core reason for a decision to authorise donation in this situation? Another area where extreme utilitarianism can subtly occur is in the promotion of LDT to shorten waiting lists irrespective of whether it is the *optimum remedium* - an approach that could only be acceptable if it were a transparent non-compulsory policy where donor and recipient could freely choose living donation as an act of social solidarity.

The 4 core principles of medical ethics<sup>30</sup> - beneficence, non-maleficence, autonomy and justice - are novel in their application to LDT - both in their own right and when

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<sup>29</sup>Reprinted in Appendix 1 of WHO's Legislative Responses To Organ Transplantation, *Martinus Nijhoff*, 1994.



meshed with philosophical theories. While it is usual to encounter beneficence and non-maleficence in the consideration of limits placed on acceptable rationale for conducting medical procedures, such procedures do not normally involve a need to balance up the equation in the context of two people (the donor and the recipient) as individuals and as a pair. What does the fact that the donor is acting as a ‘rescuer’ mean for the circumscription of self-determination by non-maleficence - for instance the circumscription of levels of permissible detriment to the donor?<sup>31</sup> What impact do beneficence and non-maleficence considerations - for the recipient, medical enterprise and the donor - have on determination of what level of financial exchange is legitimate in LDT? While dangers of utilitarian abuse amplify the need for informed consent, do these dangers simultaneously mean scope for detriment to the donor, and hence donor autonomy, should be stringently limited - more so than in an ‘average’ medical procedure? What ‘supporting role,’ if any, can beneficence for the prospective recipient play in assessing limits to detriment a donor may undergo? What variations occur if the donor is incompetent? Can a societal or judicial conception of utility ever outweigh individual rights and autonomy, for instance via the development of a system that procures more cadaveric organs by presuming, in the absence of evidence to the contrary, consent of deceased persons to organ removal or insertion of a catheter or living persons to elective ventilation?

Critical ethical questions, such as these, have to be analysed both in their own right and within the context of a 3-way interaction with practice and regulation. In this Phd, increased understanding of the ethical and legal dimensions of research hitherto conducted with the actors involved in the LDT process and a programme of questionnaires unique and wide ranging in their content and number of jurisdictions

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<sup>30</sup>Developed by Beauchamp and Chidress (see *Principles of Biomedical Ethics*, Oxford University Press, 1994) subjected to a certain amount of criticism (see for instance S.Holm, Not Just Autonomy - The principles of American Biomedical Ethics, *J Med Eth*, 1995, 21, 332-338) but widely accepted and applied and cogently defended by Raanan Gillon who amongst his conclusions states that, “very few critics argue that any one of the four principles is incompatible with his or her preferred theory or approach to biomedical ethics” (Defending ‘the four principles’ approach to biomedical ethics, *J Med Eth*, 1995, 21, 323-324 at 324).

<sup>31</sup>See chapter 6.



covered.<sup>32</sup> The main empirical data from this new programme and previous research consists of:

- Statistical information relating to such matters as current waiting lists and use of cadaveric and living donor transplantation world-wide is supplemented by statistical information on these issues from transplant centres throughout Europe, derived from responses to the European Transplant Centre Questionnaire.
- A Professional Attitudes Questionnaire addresses important clinical and ethical issues such as the circumstances in which transplant professionals will consider undertaking LDT, prefer it to cadaveric donation and their general receptivity to LDT. It also yields specific information on core LDT ethico-legal issues.
- Questionnaire based interviews with donors and recipients provide further feedback on the core ethico-legal issues.
- Numerical values are assigned to European LDT statutory provisions both as an analysis in it's own right and to enable correlation of law, practice and attitudes.

Aside from empirical and strictly ethical aspects, it was apparent that no-one had yet discussed all the key ethico-legal dimensions of LDT within one document. Examinations of transplant law such as Fuenzalida-Puelma's survey of legislation pertaining to 16 South American countries,<sup>33</sup> the World Health Organization's recent book 'Legislative Responses to Organ Transplantation',<sup>34</sup> and EUROTOLD's LEGISEARCH database<sup>35</sup> are basically foundations for analysis of the ethico-legal dimensions of LDT. A regulatory framework for LDT is the main method of stipulating the ethical parameters within which LDT may acceptably take place.

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<sup>32</sup>There was a study of attitudes amongst 148 European Transplant Centres (see Editorial, *Lancet*, 1982, ii, 696) but this was back in the early 1980's and covered a much narrower range of countries than the EUROTOLD investigation. The EUROTOLD project has also developed a Donor Health Registry with a donor health form designed to elicit information about tests conducted on donors and the medical consequences of donation. Data return is still in it's infancy and consequently this work is not significantly discussed. The central intention of the form and Registry is to elicit a large body of data on the long term health consequences of donation. This will have important consequences in helping to assess any long term risks of donating a kidney, integrating this assessment into information provided to potential living donors and recipients and whether the amount of risk is ethically acceptable and within legally permissible limits.

<sup>33</sup>Organ Transplantation: The Latin American Legislative Response. In S.S.Connor and Fuenzalida-Puelma (eds.) *Bioethics: Issues and Perspectives*, *Pan American Health Organization*, 1990, 67-86.

<sup>34</sup>*Martinus Nijhoff*, 1994.

<sup>35</sup>Available on the internet at <http://maths.ac.uk:2080/MedStats/Eurotold>



LDT is a classic example of Price's observation that the time has arrived when medical decision making has come to be perceived as a matter of public, and not just private, concern.<sup>36</sup> Eser has identified 3 functions of law, which as Price has noted, are all appropriate to LDT.<sup>37</sup> *Firstly*, the norm setting function, reinforcing certain values and interests as requiring protection against infringement. *Secondly*, a protective function, balancing the protected values against other interests, providing sanctions for abuses and minimising risks to patients and others. *Thirdly*, a regulative or declarative function, securing clarity and certainty in handling controversial areas. In addition, creating an appropriate framework for LDT involves considering the roles of national policy and professional guidelines, centre policy and attitudes and the interests of potential donors and recipients. The key issues examined include:

- the legality of LDT and legal preconditions for conducting it;
- practitioner disclosure of information pertaining to LDT to donors and recipients *and* requirements of ensuring that information disclosed is understood;
- voluntariness and pressure in LDT, including limits on certain classes of donor in this context and acceptable levels of informedness that voluntarism implies;
- issues relating to competency and legality of donation in the context of minority and adult incapacity; *and*
- financial exchange in LDT including the buying and selling of organs for profit and other levels of payment particularly as they relate to the donor.

Depth of investigation in these areas is built on a unique world-wide comparative analysis of transplant legislation and general principles of law as they relate to LDT.

## **1.2. Research Methodologies Adopted.**

The field of research methodology includes a multiplicity of often irreconcilable philosophical theories and an even greater number of approaches based upon them.<sup>38</sup>

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<sup>36</sup>D.P.Price, The Scope and Function of Living Organ Donor Transplant Laws, *Trans Proc*, Dec 1996.

<sup>37</sup>See Price *ibid*.

<sup>38</sup>See e.g. N.K.Denzin and Y.S.Lincoln (eds.), *Handbook of Qualitative Research*, Sage, 1994.



Theories can be broadly divided into two categories, those based on positivism and those adopting an alternative approach. Respectively these categories have spawned quantitative and qualitative approaches. There is an increasing tendency toward hybridisation, with researchers from each category becoming more eclectic in their approach.<sup>39</sup> This research reflects that trend and uses a wide range of approaches and techniques.<sup>40</sup>

Positivism is included in the research via the measurement and analysis of causal relationships between variables i.e. quantitative methodology.<sup>41</sup> This can particularly be seen in chapter 9 which assesses professionals attitudes and practice in living donor transplantation. However, the overarching approach to this investigation is qualitative in respect of it's multi-method focus<sup>42</sup> and deliberate attempt to gain an in-depth and rounded understanding of the subject matter. The main methods used were:

- Comparativism (in chapters 4-8 for investigating different ethical approaches to understanding and resolving major ethical issues in LDT and different legal frameworks of regulation<sup>43</sup> and in chapters 2-3 and 9-10 attitudes, practice and experience in LDT are the subject of comparative analysis);
- Psychology (assessing motivations in donation and other aspects of the consent process including informing of prospective donors and examination of pressure and voluntarism and a person-centred psychological approach was used in donors and recipient interviews and in an analysis of consent theory, practice and law<sup>44</sup>);

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<sup>39</sup>Ibid at p5.

<sup>40</sup>See e.g. C.Nelson et al., *Cultural Studies*, In L.Gossberg et al., *Cultural Studies*, *Routledge*, 1992, 1-16.

<sup>41</sup>The basic tenets of pure positivism are rejected for several reasons: *Firstly* the central tenet of pure positivism as "value free objectivist science" is incongruent with the whole notion of ethical investigation as an evaluation of the relative merits of different value systems (J.W.Carey, *Communication as Culture: Essays on Media and Society*, *Unwin Hyman*, 1989 at p99). *Secondly* it is clear to this author that value choices are inevitably made throughout research Value choices are expressed in the design and aim of the research, the actual collection of data, the interpretation of the findings and the use that is made of them (T.May, *Social Research: Issues, Methods and Process*, *Open University Press*, 1993, 35).

<sup>42</sup>J.Brewer and A.Hunter, *Multimethod Research: A Synthesis of Styles*, *Sage*, 1989.

<sup>43</sup>Comparativism can be defined as an analysis of different practices and attitudes in order to note and understand similarities and differences and to investigate underlying patterns of development.

<sup>44</sup>See Chapter 9 for further details of this approach.



- More obviously, legal and ethical approaches to analysis were adopted. These were respectively based on conventions such as statutory interpretation and use of precedent *and* applying and balancing different philosophical theories (as they relate to medical ethics) and core principles of medical ethics.

### **1.3. Research Tools and Techniques.**

Research tools were used including:

- Literature searches and surveys;
- development and use of electronic databases for the systematic categorisation and efficient organisation and retrieval of information such as addresses, bibliography and empirical data;
- questionnaire surveys and face-to-face/telephone interviews to garner information from a sample of professionals and participants to learn about these populations as a whole<sup>45</sup> and draw out data and issues of wider significance including a relevant ethical and legal framework for living donor transplantation; *and*
- statistics as a tool for the analysis of questionnaire and interview data and for understanding other issues including those relating to supply and demand in organ procurement.

The main research technique used is coding. The purpose of coding has been defined as developing answers "into meaningful categories, so as to bring out their essential patterns."<sup>46</sup> In chapters 9 and 10 coding is used in its widest sense - as a broad "process of categorising and sorting data"<sup>47</sup> - to organise data arising from the empirical research with professionals and participants. In chapter 10 coding is used with the professional questionnaires and statistical analysis of laws in its more strict context as a statistical system of values assigned to responses with emergent data cross correlated. The donor-recipient sample presented in chapter 9 produces vital

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<sup>45</sup>R.Ferber et al., What is a Survey?, *American Statistical Association*, 1980, 3.

<sup>46</sup>C.Moser and G.Kalton, Survey Methods in Social Investigation, *Heinemann*, 1983, 414.

<sup>47</sup>K.Charmaz, The Grounded Theory Method: An Explication and Interpretation, in R.M.Emerson (ed), *Contemporary Field Research*, *Little Brown*, 1983, 111.

qualitative data but was not coded in this strict manner because it was not a formal or large enough sample from which to make probability theory based estimates of living donor and recipient population characteristics.

Miles and Huberman have distinguished between descriptive, interpretative, explanatory and astringent codes.<sup>48</sup> This research displays all four of these dimensions of coding. In chapters 9 and 10 data is sorted and categorised according to the goals of describing it, explaining it and interpreting it but in chapter 10 the astringent code is also used - i.e. massive amounts of data are astringently drawn together to produce highly refined data, in this case professional responses to a large number of hypothetical case studies are coded to produce simple scales of favourable / non-favourable attitudes towards different forms of renal treatment.

#### **1.4. Professional Research Ethics.**

Questions of professional research ethics arose and were addressed as follows:

- The patient interview and questionnaire aspect of the research was discussed extensively amongst a multi-disciplinary team before being passed on to the relevant ethical committees for approval. Participants gave informed consent prior to taking part and, in the case of the semi-structured interviews, given the option of not having them taped.<sup>49</sup> Data relating to patients has been kept in a secure space and data protection laws and ethics have been observed.<sup>50</sup> Research findings relating to donors and recipients have been written up with pseudonyms in some cases and anonymously in others. Care has been taken to exclude sensitive information of a kind that may be liable to distress donor and recipient participants. I utilised my counselling knowledge and skills during interviews and made myself available for feedback wherever practicable, particularly where sensitive issues were raised.

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<sup>48</sup>Qualitative Data Analysis, Sage, 1984, 57.

<sup>49</sup>See chapter 9.2. - the fully structured interviews were not tape recorded.

<sup>50</sup>Including not keeping identifying patient details on computer files.



- The professional questionnaires were widely distributed amongst experts coming from several different specialisms and having varying degrees of involvement in transplantation processes. A key aspect of this process was to ensure any bias toward or against particular modalities of conventional treatment of organ disease was eliminated. Case studies were also used to avoid an obviously 'defensive' approach and to assess attitudes subtly.

### **1.5. Limitations of the Investigation.**

The primary limitation of the investigation is that in the absence of an empirical comparison of naturopathic and allopathic 'treatment' of organ disease the latter, involving replacement therapy and (in the case of kidneys) dialysis, is assumed to be beneficent. The basic ethical principle, enshrined in a number of transplant laws,<sup>51</sup> that transplantation should not infringe '*primum non nocere*' indicates potential value in comparison of holistic-naturopathic and allopathic approaches given that the former, if successful, could deliver more optimal quality of life outcomes in treatment of organ disease - i.e. return of the body to a state of balanced health rather than reasonable, but restricted, quality of life and life expectancy.<sup>52</sup> Another valid reason for such a study is that the mechanistic paradigm of science within which the allopathic approach is set has been subject to strenuous criticism on several levels including it's characterisation as being:

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<sup>51</sup>See chapter 6.

<sup>52</sup>Quality of life outcomes in the mechanistic approach can be approximated as follows: Transplants last about a decade on average with the need for further transplants. There is an ever more acute shortage of organs. Waiting lists in different centres and countries vary but UK figures, which reflect a typical European position, show a patient will typically wait around two years for a kidney transplant (Gilks WR, Bradley BA et al. 'Predicting Waiting Time For a Beneficially Matched Graft', *Trans Proc*, 1987, 19, 3640-1; waiting time has increased since this study). A patient may be on dialysis while waiting, or in the event of this not being available or suitable, a transplant is usually required quickly to avert death. LDT can avert the consequences of waiting which are deleterious even for patients on dialysis. Transplantation invariably involves the necessity of a drugs regime except where organs have a perfect or near perfect match as is the case with identical twins (making LDT a cheap option in such instances). Drugs are used to suppress the immune system which would naturally reject the foreign material. This is a non-holistic process with drugs causing 'toxic side effects' as a consequence of the suppression. Steroids and cyclosporine are commonly prescribed on a permanent or long term basis - the latter has been described as having effects including; "tremors, convulsions, swelling and inflammation of the gums, abnormal growth of body hair and increased incidence of lymphoma and Kaposi's sarcoma." *New York Task Force*, 1988 at p20. Hypertension, hepatitis and cancer are also described as risks and the toxic impact can contribute negatively to internal organs including kidneys (Task Force at p14). Ironically drugs can even toxify the transplanted organ. The full impact of these drugs is uncertain.



- abusive of power in its historical suppression of a more holistic approach<sup>53</sup> and it's contemporary consequences;<sup>54</sup>
- iatrogenic,<sup>55</sup> fostering it's own counterproductivity<sup>56</sup> and in general a major threat to health in terms of it's empirical consequences;<sup>57</sup>
- misguided in it's costly dominant focus on treatment rather than prevention<sup>58</sup> with, ironically, *the failure of health - which has been fostered by the very limited*

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<sup>53</sup>Historically a new male dominated profession destroying what was ostensibly community medicine based on more holistic principles and administered mainly by women (see e.g. D.Ehenrich and B.English, *Witches, Midwives and Nurses: A History of Women Healers*, *The Feminist Press*, 1973; A.Rich, *Of Women Born: Motherhood as Experience and Institution*, *Bantam*, 1979; M.Daly, *Gyn/Ecology: The Metaethics of Radical Feminism*, *Beacon Press*, 1978)

<sup>54</sup>Illich states that, "during the last generations the medical monopoly over health care has expanded without checks and has encroached on our liberty with regard to our own bodies. Society has transferred to physicians the exclusive right to determine what constitutes sickness, who is or might become sick, and what shall be done to such people...The social commitment to provide citizens with almost unlimited outputs from the medical system threatens to destroy the environmental and cultural conditions needed by people to live a life of constant autonomous healing" (*Limits to Medicine*, *Penguin Books*, 1977 at 13-14). Transplantation itself is at the forefront of the centralisation of medicine and it's technical advance, "(t)herapies such as organ transplantation, open heart surgery and cancer chemotherapy move medicine one step further toward the bureaucratization, organization and specialization that is characteristic of almost every sphere in modern industrial society, particularly those influenced by technological advances. Medicine is becoming more of a specialized team operation and less of a relationship between an individual family physician and his patient" (R.G.Simmons et al., *Gift of Life*, 1977, *Wiley and Sons*, p380). Ironically, treatments forged within an allopathic system of responding to organ disease can become a justification for the limited attention paid to a truly patient-centred approach because they are difficult or impossible to operate at a grass roots level, "only relatively large hospitals can support so many personnel and special facilities. Transplantation, therefore, like other advanced medical technologies, tends to be concentrated in a number of large centers throughout the country... patients must adjust to the new experience of travelling away from their communities to these centers for medical treatment." (R.G.Simmons, *Gift of Life*, *Wiley and Sons*, 1977, p382).

<sup>55</sup>P.E.Sartwell, 'Iatrogenic Disease: An Epidemiological Perspective', *International Journal of Health Services*, 1974 (winter), 89-93.

<sup>56</sup>"...some drugs are addictive, others mutilating, and others mutagenic, although perhaps only in combination with food colouring or insecticides. In some patients, antibiotics alter the normal bacterial flora and induce a superinfection, permitting more resistant organisms to proliferate and invade the host. Other drugs contribute to the breeding of drug resistant strains of bacteria.... Unnecessary surgery is a standard procedure.... In a complex technological hospital, negligence becomes 'random human error' or 'system breakdown', callousness becomes 'scientific detachment', and incompetence becomes 'a lack of specialized equipment.' The depersonalization of diagnosis and therapy has changed malpractice from an ethical into a technical problem." Illich, *Limits To Medicine*, *Penguin*, 1977 at 39.

<sup>57</sup>Illich suggested that the medical system has become 'sickening' for three reasons; "It must produce clinical damage that outweighs it's potential benefits: it cannot but enhance even as it obscures the political conditions that render society unhealthy: and it tends to mystify and expropriate the power of the individual to heal himself and to shape his or her environment....The medical and paramedical monopoly over hygienic methodology and technology is an example of the political misuse of scientific achievement to strengthen industrial rather than personal growth." *Limits to Medicine*, *Penguin*, 1977 at 16.

<sup>58</sup>Ethical issues are raised about the cost of health care including conventional treatments of organ disease, "...now questions are being raised about the cost of saving lives that could not be saved before.



*resources allocated for successful prevention - regularly used to support the introduction of expensive new treatments;*<sup>59</sup> and

- based on an outmoded paradigm of science which has been superseded by a more holistic approach.<sup>60</sup>

Of course there are also more absolute criticisms of transplantation itself that should be mentioned including the view that it is an unacceptably artificial method of prolonging life; a view that can be connected with religious and spiritual perspectives concerning the nature of personhood, the acceptability of using another person's body part<sup>61</sup> or simply the observation that its use relies on the 'artificiality' of suppression of intrinsic human functions.<sup>62</sup>

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Should scientists be encouraged to develop expensive technologies that potentially can extend the lives of select groups of the fatally ill? ... in some ways the experience of organ transplantation parallels other less dramatic but almost equally expensive therapies and alerts us to the possible effects of future medical advances." R.G.Simmons et al, *The Gift of Life*, 1977, *Wiley & Sons*, p3.

<sup>59</sup>In some sense those making profit out of mechanistic technologies have *commercial vested interest in ill-health and a specific interest in propaganda that deflects attention from effective prevention or non-mechanistic treatment of disease because it's consequence would be lower profit for them.*

<sup>60</sup>The Newtonian so-called 'mechanistic' paradigm of physics which gave rise to the medical model has been superseded by a quantum paradigm taken by most prominent 20th century scientists as indicating a humanistic, holistic basis for science (Rychlak, *The Psychology of Rigorous Humanism*, *Wiley*, 1977 at 193). Bohm has suggested that, "we must drop the mechanistic order" (*Wholeness and The Implicate Order*, *Routledge and Kegan Paul*, 1980, 175). Dossey has noted that, "(w)e have built a model of health and illness, birth and death, around an outmoded conceptual model of how the universe behaves, one which was fundamentally flawed from the beginning. While the physicists have been painfully eliminating the flaws in their own models, we have in medicine ignored these revisions totally. We find ourselves thus with a set of guiding beliefs that are as antiquated as are body humors, leeching and bleeding" (*Space, Time and Medicine*, *Shambala*, 1982).

<sup>61</sup>The use of cadaveric transplantation meets objections regarding interfering with 'the process of death' and this has resulted in minimal use in countries like Japan. Some Muslim communities have low procurement rates coinciding with religious objections (EUROTOLD discovered this in Leicester for instance).

<sup>62</sup>Illich, *Limits to Medicine*, *Penguin*, 1977 at p179. Even stronger objections exist to the experimentation and proposed use of animal organs. Many animals have died in this process and the development of transgenics is seeing the breeding of new 'mutagenic' species of animals raising fundamental ethical questions.



## **Chapter 2 The LDT Context - Evaluating the Organ Shortfall and Possibilities for Expanding Cadaveric Procurement.**

### **2.1. Introduction**

The justification for a medical procedure in an individual case can rarely be simply that its benefits outweigh its detriments. Usually other options must also be considered. In transplantation donor detriment in LDT sets up a presumption in favour of using CDT which would be almost the exclusive source of organs but for the organ shortage. The critical first step in uncovering the circumstances for justifiable use of LDT is to evaluate the current extent of the shortfall in organs and its significance *and* determine the ethical and practical limits to addressing the shortfall through increased levels of CDT.

### **2.2. Evaluation of the Extent of the Organ 'Shortfall.'**

Since the 1950's, transplantation rates have been rapidly increasing but it was not until the 1980's and the advent of cyclosporine that they started to reach a very significant level. Increasing 'success rates' for organ transplantation, and escalating diagnosed incidence of organ disease (particularly ESRF), have fuelled the demand for organs.

#### **2.2.1. Waiting List Trends.**

The 1990's trend as a whole has been one of significant increases in the number of people waiting for kidneys.<sup>1</sup> USA,<sup>2</sup> Belgium,<sup>3</sup> Germany,<sup>4</sup> Greece<sup>5</sup> and The Netherlands<sup>6</sup> are individual countries which potently reflect this. The EUROTRANSPLANT kidney transplant waiting list increased from 9,445 in 1989 to 12,849 in 1995 while the UKTSSA list increased from 3,704 in 1989 to 5,286 in June 1996. However, there is a sub-trend, with a few major transplant regions having reduced waiting lists including SCANDIATRANSPLANT (Scandinavia),<sup>7</sup> EFG (France)<sup>8</sup> and most remarkably ONT

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<sup>1</sup> Graphs 2 and 3 - see pages 53 and 54.

<sup>2</sup> Graph 2 - see page 53. From 1989 to 1995 more than 11000 have been added to the US waiting list representing an increase of approximately two thirds.

<sup>3</sup> Graph 7 - see page 58.

<sup>4</sup> Graph 9 - see page 60.

<sup>5</sup> Graph 10 - see page 61.

<sup>6</sup> Graph 11 - see page 62.

<sup>7</sup> SCANDIATRANSPLANT down from 1214 in 1992 to 944 in 1994.

<sup>8</sup> See Graph 8 at page 59, EFG down from 4529 to 4516 in 1994.



(Spain)<sup>9</sup> which has been adopting a much more rigorous and co-ordinated procurement policy.<sup>10</sup> Outside of kidney transplantation the trend in liver, pancreas and heart lung is almost pan European increases which are mirrored in the United States.<sup>11</sup> Exceptionally, heart procurement rates have stabilised or decreased in most areas.<sup>12</sup>

### 2.2.2. Organ Procurement Levels.

Overall, kidney organ procurement levels per million population during the 1990's are relatively stable. Typical figures are: EUROTRANSPLANT 28.7 p.m.p. in 1992 to 28.8 p.m.p. in 1995; SCANDIATRANSPLANT 37.5 p.m.p. in 1992 to 34.4 p.m.p. in 1995; UKTSSA 29.9 p.m.p. in 1992 to 31.2 p.m.p. in 1995;<sup>13</sup> and LUSO Transplant 36.7 in 1992 to 37 p.m.p. in 1995.<sup>14</sup>

The period 1992-1995 confirms the assessment of 1990-1992 by the authors of the Kings Fund Report that the 1990's have seen a plateau in procurement following large increases sustained in the 1980's.<sup>15</sup> There are a few exceptions to this trend - e.g. Spain increasing it's kidney transplantation quite sharply from 38.8 p.m.p. in 1992 to 46.9 in 1995 and, conversely, France decreasing from 30.5 p.m.p. in 1992 to about 26 in 1995.

Inside the above 'Western block' countries, only Italy and Greece have kidney transplantation rates that are very low, whereas, in most other countries of the world there is an almost universally low rate of kidney transplantation p.m.p.<sup>16</sup> Of former Central and Eastern European countries the average rate of transplantation p.m.p. is very low,<sup>17</sup> the Czech Republic excepted.<sup>18</sup> Countries like Romania and Bulgaria have negligible transplantation and Albania has yet to start a programme. Outside Europe /

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<sup>9</sup>See Graph 13 at page 64. ONT down from 5151 in 1992 to 4621 in 1994

<sup>10</sup>See 2.3.2.4.

<sup>11</sup>See respectively Council of Europe report on transplantation (1996) and UNOS statistics.

<sup>12</sup>Ibid.

<sup>13</sup>See Graph 17 at page 68.

<sup>14</sup>Ibid.

<sup>15</sup>B.New et al., Research Report 18 at p15.

<sup>16</sup>South America typifies this position; Argentina has one of it's higher procurement rates of approximately 4 p.m.p. - about one sixth of the average European country (see O.Lopez Blanco, Significant Increases of Organ Procurement in Argentina, 1992-1994, *Trans Proc*, 1996, 28(1), 98-100).

<sup>17</sup>See Graph 19 at page 70.

<sup>18</sup>Liason with Ferenc Perner, Semmelweis Medical Institute, Budapest, Hungary (PECO Participant) informed the EUROTOLD project of the high rate in the Czech Republic which has now joined EUROTRANSPLANT.



USA only a handful of countries, including Israel and Cyprus<sup>19</sup> have a reasonable rate of kidney transplantation p.m.p.

### **2.2.3. Conclusions on the Extent of Organ Shortfall.**

Comparisons of respective national positions must be approximate and generalised because of variations in the criteria used for acceptance onto the waiting list.<sup>20</sup> In 1989, G.Koostra et al.,<sup>21</sup> stated that in Western Europe less than half of those persons deemed suitable for organ transplant therapy are transplanted. The situation has become progressively worse with a spiralling supply and demand gap in most transplant areas.<sup>22</sup>

Whilst at least 40 kidneys p.m.p. are typically required to match demand there are only about 12 countries world-wide whose rate of kidney transplantation reaches above 30 p.m.p.<sup>23</sup> Nevertheless, a few countries (e.g. Belgium, Austria, Eire, Portugal and Spain) reach high levels of kidney transplantation p.m.p. with only low percentage use of living donation.<sup>24</sup> Spain and Eire have reduced the gap between supply and demand whilst relying almost solely on cadaveric donation. Analysis of the options for improving cadaveric procurement may provide some clues as to whether such success without reliance on LDT can be replicated in other countries.

### **2.3. Practical and Ethical Viability of Utilising Cadaveric Procurement Solutions to the Organ Shortage.**

The primary cause of the organ shortage, in a system that views transplant as the 'gold standard' response to organ disease, is the increasing incidence of end stage renal

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<sup>19</sup>See Graph 18 at page 69.

<sup>20</sup>Austria, Belgium and West Germany have high waiting lists per million population compared with most other European countries but they also have high acceptance for transplant rates and high transplant rates. Cohen and Persijn, 1992, Eurotransplant Foundation Annual Report 1991, EUROTRANSPLANT Foundation, Leiden, Netherlands. Also EDTA 1992 statistical report. The position is even more contrasted with the United States of America which has a very broad treatment programme, "the USA treatment rate (incidence) was 2.2 times higher than in Canada and 3.8 times higher than the combined European rate. Only one European country, Austria, had a treatment rate more than half as high as that of the United States." J.K.Iglehart, The American Health Care System: The End Stage Renal Disease Programme, *New Eng J Med*, 1993, 328(5), 366-371

<sup>21</sup>*Trans Proc*, 1989, 20, 809.

<sup>22</sup>See Graphs 1-13 at p52-64.

<sup>23</sup>See Graph 19 particularly at p70.

<sup>24</sup>See Graph 17 at page 68 and Graph 35 at page 86.



failure.<sup>25</sup> This means that for supply to meet demand increases in procurement will be needed to clear current waiting lists *and* further increases will be needed to match increasing levels of demand. If transplantation is the treatment of choice for most non-marginal ESRF sufferers, powerful strategies are needed to optimise procurement. Cadaveric strategies can be divided into 3 areas:

- *First*, those utilising methods involving new classes of donors;
- *Secondly*, organisational factors internally and in relation to society; *and*
- *Thirdly*, societal factors.

### **2.3.1. Utilising Methods Involving New Classes of Cadaveric Donor.**

Price has highlighted the vagueness and ambiguity surrounding ethical and legal issues in elective ventilation and use of non-heart beating donors.<sup>26</sup> Both these methods need examination as strategies that could potentially yield large increases in organ procurement.

#### **2.3.1.1. Use of Non-Heart Beating Donors.**

Procurement could be increased by around 20-40% with use of non-heart beating donors (NHBD's).<sup>27</sup> The 2 methods for use are, *firstly*, inserting of a catheter tube through the groin area of the deceased into the cadaver by which means the kidney can be chilled in situ as a stop-gap measure to maintain the organ until relatives are available to offer consent (or refusal) to organ removal; and, *secondly*, the University of Pittsburgh Medical Center protocol where patients with profound brain damage are removed from ventilatory support, with relatives' or patients' consent and their organs are removed after death. The first approach has the advantage of not presuming consent of the deceased to

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<sup>25</sup>For instance the quantity of people registered as having end stage renal disease registered in the United States of America more than doubled between 1975 and 1988 see 899-900 *ibid*.

<sup>26</sup>DPT Price, Organ Transplant Initiatives: The Twilight Zone, *J Med Eth*, 1997, 23, 170-175 at 170.

<sup>27</sup>See e.g. R.Schlumpf et al., Transplantation of Kidneys From Non-Heart-Beating Donors: Protocol, Cardiac Death Diagnosis, and Results, *Trans Proc*, 1996, 28(1), 107-100; G.Kootstra et al., Twenty Per Cent More Kidneys Through a Non-Heart Beating Programme, *Trans Proc*, 1991, 23, 910-911 and Daeman et al.'s more recent study at Koostra's Maastricht centre which indicated that a non-heart beating programme contributes 40% (J.H.C.Daeman, Non Heart-Beating Donor Program Contributes 40% of Kidneys For Transplantation, *Trans Proc*, 1996, 28(1), 105-106). In this procedure kidneys can be removed after the cessation of heartbeat - studies indicate this is feasible up to 110 minutes after cessation of heart beat. For ethical analysis of this area see F.Th.De Charro et al., Donor Recruitment in F.Th.De Charro et al., Europe in Systems of Donor Recruitment, *Kluwer*, 1992, 5

organ removal but is applying presumed consent to insertion of the catheter! The Kings Fund Institute Report stated that,

"such a small scale procedure may prove ethically acceptable. But if presumed consent legislation proves unacceptable, the precise ethical distinction between inserting a catheter and removing an organ should be clarified. Such a distinction is not obvious - both involve cutting a corpse without consent. There is a danger of inconsistency here. Ultimately, the ethical issues revolve around consent in both cases, and not the nature of the act to which consent is, or is not, presumed."<sup>28</sup>

If such a procedure can rightly be sanctioned at all, it should be subject to specific enabling legislation and wide public and professional agreement. The prima facie case is to prioritise LDT's that involve low levels of prospective detriment above the use of a method that violates the right to choose the manner of treatment of one's body after death. As a matter of degree, however, use of the catheter method is preferable to a presumed consent organ procurement system. It is also preferable to the Pittsburgh protocol under which organs are removed after 2 minutes of 'irreversible' loss of cardiac function which is before brain stem death has occurred. Even accepting the reliance on cardiopulmonary criteria for establishing death, 2 minutes of loss of function is not proof of irreversibility. The protocol, by current standards, must be regarded as unacceptable as through causing grievous bodily harm to a living person.<sup>29</sup> Evidence of consent by the patient (e.g. through an advance directive) cannot be sufficient to justify this harm but could justify use of the catheter method of removal.

#### 2.3.1.2. Elective Ventilation.

The Royal Devon and Exeter Hospital was the first British hospital to develop an elective ventilation protocol.<sup>30</sup> This involved, with relatives consent, transferring patients in deep irreversible coma and believed to be dying imminently of intracranial haemorrhage to intensive care, so that artificial ventilation could be commenced immediately respiratory arrest occurred and until brain stem death tests could be satisfied. The organ

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<sup>28</sup>Bill New et al., Kings Fund Research Report, 18 at 66.

<sup>29</sup>For a further discussion of the ethical and legal issues arising from this method of NHBD use see DPT Price, Organ Transplant Initiatives: The Twilight Zone, *J Med Eth*, 1997, 23, 170-175.

<sup>30</sup>Feest T, Riad H et al., Protocol for Increasing Organ Donation After Cerebrovascular deaths in a District General Hospital, *Lancet*, 1990, 335, 1133-1135.



procurement result was evaluated as a 50% increase in organs over a four year period.<sup>31</sup> The Kings Fund Report suggested that,

"Elective ventilation has provided initial evidence of a substantial impact on donation rates; implementation of this procedure is recommended if legal and ethical questions relating to the interests of the potential donor can be resolved."<sup>32</sup>

Elective ventilation for transplantation purposes was declared an unlawful battery by the Health Departments of England and Wales in guidelines of October 1994.<sup>33</sup> The legal problem stems from the fact that the procedure is not in the patients best interests. The BMA has called upon the government to introduce legislation permitting use of elective ventilation for organ transplantation.<sup>34</sup> However, with a living patient<sup>35</sup> there are not just legal but ethical concerns to evaluate, including: the view that "deliberately prolonging a patient's dying is unacceptable for any reason;"<sup>36</sup> the possibility that it might increase the number of patients in a persistent vegetative state (PVS); *and* the view that scouting around an ICU unit for organs offends the dignity of the dying process.<sup>37</sup>

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<sup>31</sup>B.New et al., Kings Fund Research Report, 18 at 55. An opponent of elective ventilation has pointed out that the number of donors involved was not statistically significant (G.Routh, *Elective Ventilation For Organ Donation - The Case Against, Care of The Critically Ill*, 1992, 8, 60-61). However, the increase is so extensive as to warrant further investigation. Attention has been drawn "to the relatively small impact such a policy would have on the intensive care community, whilst having a potentially enormous impact on transplant activity." B.New et al., (Kings Fund Report, 18 at 56). Estimated that it a national system would result in 0.46% extra usage of ICU beds.

<sup>32</sup>B.New et al., Kings Fund Research Report, 18 at p8

<sup>33</sup>The use of elective ventilation before the establishment of brain stem death would constitute a battery in law unless prior consent was obtained from the patient. Prior consent from the relatives is not adequate because even in cases of incapacity any treatment must be in the patient's best interests which elective ventilation is not in such an instance as this where it is simply to facilitate the successful utilisation of the patient's organs. The alternative would be where a patient has made an advance directive consenting to this procedure but the legal validity of advance directives is uncertain. For the challenge to the legality of LDT see A.Somerville, *Medical Ethics Today: It's Practice and Philosophy*, BMA, 1993. The PIVOT (the potential of elective ventilation for organ transplantation) study was proposed to examine issues in elective ventilation but was abandoned due to the questionable legality of elective ventilation (Kings Fund Report, B.New et al. at 56).

<sup>34</sup>Report of the BTS Working Party on Organ Transplantation, *BTS*, 1995 at p32

<sup>35</sup>It is hardly convincing, and runs against the brain stem death test, to suggest that "such patients die when breathing ceases; elective ventilation does not prolong the act of dying, for one is ventilating a corpse" (A.Nicholls and H.Riad, *Organ Donation* (letter), *BMJ*, 1993, 306, 517-518).

<sup>36</sup>G.R.Park et al., *Organ donation* (letter) *BMJ*, 1993, 306, 145.

<sup>37</sup>Concerns exist that the procedure might leave a number of persons in a persistent vegetative state and also that it offends the dignity of the dying process, "I take exception to the idea ... that we should scout around the wards, look for patients about to die and take them to the Intensive Care Unit, intubate them and ventilate them until they are brain dead so that their organs can be used for the purposes of transplantation" (D.Bihari (1993) quoted from the Kings Funds Report at p65).

Justifying the procedure as not being against the patients best interests may be acceptable but only where this reflects the clear will of the patient (e.g. expressed in an advanced directive) rather than simply the utilitarian ideals of professionals and/or relatives. Elective ventilation reflecting the patient's will may be acceptable (perhaps somewhat excepting concerns about PVS) - although it will not be likely to greatly increase organ procurement rates in the short term.<sup>38</sup>

### **2.3.2. Organisational Factors in Cadaveric Procurement.**

Several changes in the organisational structuring of the procurement system might increase organs available for transplantation.

#### **2.3.2.1. Links Between I.C.U.s and Transplant Units.**

Better links between I.C.U.'s and transplant Units may result in a significant increase in available organs. Gore's survey of intensive care units in the UK indicates that better funding of ICU's may be required.<sup>39</sup> This is confirmed in the BTS report which calls for urgent address of the national shortage of ICU beds having concluded that "ICU provision may be an important constraint on organ donor numbers."<sup>40</sup>

#### **2.3.2.2. Size of Procurement Area.**

Evidence from the US indicates that organ procurement organisation size is correlated to public willingness to donate cadaver organs, smaller organisations having more success.<sup>41</sup> Spain's localised co-ordination and procurement system<sup>42</sup> may have positively impacted its transplant rates in the 1990's.

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Any future proposal to use elective ventilation will need to take account of public attitudes as it is well documented that these can have a serious impact on donation rates (See T.Patel, France's Troubled Transplant Trade, *New Scientist*, 1993, 3 July, 12-13).

<sup>38</sup>Advance directives are only enforceable in some jurisdictions and, equally to the point, they are not commonly made in most.

<sup>39</sup>Often competition for beds leads to a practitioner withdrawing or not instituting ventilatory or haemodynamic support which can lead to potential donors failing to become actual donors. See S.M.Gore, Intensive Care Unit Funding: Survey of Staffing and Bed Occupancy in November 1989, *Care of The Critically Ill*, 1991, 8, 79-80.

<sup>40</sup>BTS Working Party Report on Organ Donation, *BTS*, 1995 at p29

<sup>41</sup>Probably because of the more personal contact available, lesser transportation times and a knowledge amongst the relevant local community that those around them will be the ones to benefit (July 1990 Report of the United Network for Organ Sharing reported by F.Rapaport et al., *Trans Proc*, 1991, 23, 899-900).



#### **2.3.2.3. Geographical and Infrastructural.**

The geography and infrastructure of a country and its spread of transplant centres are a potential factor influencing procurement,

"In general, the less densely populated a country the longer the average distance between hospitals, transplant centres, and those suffering from a cerebrovascular accident. All these factors will make it harder to reach and transport patients to ICU, and more difficult and time consuming to collect and transport organs without affecting their suitability. Cadaveric organ procurement, it could be argued, is therefore more problematical in less densely populated countries."<sup>43</sup>

Comparing 17 countries, the Kings Fund Report indicated that five of the bottom six cadaver procurement nations also corresponded to the lowest population density nations.<sup>44</sup> Some improvements in transplantation rates will inevitably occur through improved transportation and infrastructure.

#### **2.3.2.4. Systems of Co-ordination.**

The Spanish transplant system involves a comprehensive and sophisticated network of co-ordination applying to all donating hospitals not just those that actually do transplants. The co-ordination team involves doctors and nurses and works at a localised level.<sup>45</sup> There has been a sharp increase in levels of procurement since the inception of this system. Spain is now a world cadaveric procurement leader.<sup>46</sup> This could be attributable to other factors such as worsening road traffic death rates but is probably at least partly a product of co-ordination changes which might be replicable in other

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<sup>42</sup>For a commentary on the Spanish approach see B.Miranda et al., Integrated Ways to Improve Cadaveric Organ Donation, *Trans Proc*, 28(1), 1996, 96-97.

<sup>43</sup>B.New et al., Kings Fund Research Report, 18 at p28. This is common sense for countries like Norway which has just one transplant centre in the South (Oslo) and is a disparate population with limited transportation facilities in some areas.

<sup>44</sup>These five were Finland, Sweden, Norway, Australia and Canada with the exception being the United Kingdom, B.New et al., *ibid*. They suggested that population densities of less than 20 per square km have a significant impact on a country's ability to procure cadaveric kidneys.

<sup>45</sup>For a commentary on the Spanish approach see B.Miranda et al., Integrated Ways to Improve Cadaveric Organ Donation, *Trans Proc*, 28(1), 1996, 96-97.

<sup>46</sup>See Graph 21 at page 72.

countries<sup>47</sup> - for instance, the BTS Working Party Report, after examining the Spanish model, concluded that, "(d)velopment of the UK co-ordinator network should undoubtedly be a central element in the drive to increase organ donation."<sup>48</sup>

### **2.3.3. Societal Factors in Cadaveric Procurement.**

#### **2.3.3.1. Objections to Transplantation**

Cadaveric procurement figures in the United Kingdom also indicate that in about 30% of cases the deceased potential donor does not become an actual donor because of the refusal of his / her relatives to allow donation to occur.<sup>49</sup> Cleiren's study<sup>50</sup> indicates this is partly due to the way relatives are asked<sup>51</sup> whilst other studies relate refusal partly to factors like ethnic background and age.<sup>52</sup> Some refusals are clearly connected to real objections to transplantation. Some people will not donate organs for religious,<sup>53</sup>

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<sup>47</sup>However Persijn has commented that "as the definition and tasks of a transplant co-ordinator differ from country to country. Some are more involved in administrative work such as registration of transplant candidates, looking after the logistical aspects (transportation arrangements, financial aspects etc.) and follow-up activities, while others are really involved with organ donation, assisting and advising local doctors in charge of a potential donor. Additionally, the professional background of transplant co-ordinators varies from nurses to anaesthesiologists, from psychologists to surgeons in training." How Severe is Organ Shortage in Eurotransplant p9 in Organ Shortage the Solutions (ed J.L.Touraine, *Kluwer*, 1995). A comment from the Spanish about their own system probably sums the situation up accurately, "we do not really know whether the particular approach used in Spain to organise organ procurement and transplantation can be directly applied to other countries with different health systems. Nevertheless, we hope the information on the Spanish system can be useful when organisational structures are under consideration in other countries." R.Matesanz, *Organ Procurement in Spain: The National Organization of Transplants*, 167-177 at 176 *ibid*.

<sup>48</sup>BTS, 1995 at p30.

<sup>49</sup>S.M.Gore et al., *Organ Donation From Intensive Care Units in England and Wales: Two Year Confidential Audit of Deaths in Intensive Care*, *BMJ*, 1992, 304, 349-355.

<sup>50</sup>Which indicated the following 'complaints' from families; \*Procedure too hasty, there was no time to think it over \*Doctor was too businesslike, showed no emotion \*Not enough information was given \*There was neither opportunity nor time enough to say the last 'good-bye' to the deceased \*Consent was asked at the wrong moment (before the death was confirmed; at the same time that the family was informed of the death of the relative) \*Family felt pressured by request for organs \*After consent was given there was a second request for more organs. (see M.P.H.D.Cleiren, *Life After Giving. A Research Into the Experience of the Next of Kin of the Organ and/or Tissue Donor*, *D.S.W.O. Press*, 1992).

<sup>51</sup>Medical professionals are not always comfortable with dealing with relatives. One survey indicated that a sizeable percentage of U.S. neurosurgeons are uncomfortable with dealing with social issues like requesting organ donation (J.M.Prottas and H.L.Batten, *Neurosurgeons and The Supply of Human Organs*, *Health Affairs*, 1989, 119-131. 10% of all US Neurosurgeons were surveyed by questionnaire).

<sup>52</sup>See e.g. D.Noury, *Information on Relatives of Organ and Tissue Donors. A Multicenter Regional Study for Consent or Refusal*, *Trans Proc*, 1996, 28(1), 135-136 which in an analysis of 300 interviews indicated that refusals decreased sharply as age of the relatives being asked increased.

<sup>53</sup>See Kostakis et al., *Trans Proc*, 1990, 22, 1432-1433.



spiritual or other reasons.<sup>54</sup> Around 15% of people have indicated in public surveys they are against donating their own organs after death.<sup>55</sup> About half of this number say they would not even accept a transplant for themselves.<sup>56</sup> Only about 30% of people have a donor card (not all of whom will carry them)<sup>57</sup> and recent studies in USA<sup>58</sup> and Holland<sup>59</sup> indicate only 36% and 38% of people respectively claim to be potential organ donors. In totality the evidence suggests,

"it is not clear to what extent the rate of relatives' refusal to give consent to donation can be reduced below present levels."<sup>60</sup>

### **2.3.3.2. The Societal System for Organ Procurement.**

De Charro et al.,<sup>61</sup> distinguish five types of organ procurement system:

1. Collective solidarity (the compulsory taking of organs from deceased persons);
2. Strict opting out (reusing donor organs in all cases where no legal evidence of a decision to opt out of donating is available);
3. Broad opting-out (next of kin may refuse to donate);
4. Broad opting-in (the next of kin have the authority to opt-in to donating where there is no evidence of a prior decision by the deceased); *and*
5. Strict opting-in (donation only occurs if deceased has made his/her willingness to donate known).

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<sup>54</sup>E.g. misunderstanding or misconceptions about transplantation or simply intuitive feelings not to donate.

<sup>55</sup>1992 surveys by OPCS, RSGB and Gallop Poll. The combined results of these 3 major recent surveys of attitudes to donating own organs after death indicates around 70% of people in favour with about half of the remainder neutral or undecided.

<sup>56</sup>For instance reservations about the medico-legal method of establishing death were 7% in the OPCS survey and 5% in a survey conducted by Wakeford and Stepney, *Br J Surg*, 1989, 76(5), 435-439.

<sup>57</sup>Statistical surveys are the OPCS Omnibus Survey, September 1992; RSGB Omnibus Survey, July 1992 and Gallup Poll, April 1992. A Poll conducted by SOFRES among the French population in 1992 shows that 37% those who would not donate had religious and moral motives, 22% were concerned about bodily integrity not being protected and 26% were uncertain as to why they were against organ donation.

<sup>58</sup>D.S.Kittur et al. Incentives for Organ Donation, *The Lancet*, 1991, 338, 1441-1443.

<sup>59</sup>W.Kokkedee, Kidney Procurement Policies In the Eurotransplant Region: 'Opting in' Versus 'Opting Out', *Social Science and Medicine*, 1992, 35(2), 177-182.

<sup>60</sup>Kings Fund Research Report, 18 at p46.

<sup>61</sup>F.Th.De Charro et al., Donor Recruitment in F.Th.De Charro et al. (ed), *Europe in Systems of Donor Recruitment*, Kluwer, 1992, 5.

The fifth alternative most respects donor autonomy but is not operated in practice in any country of the world - probably because of the small number of people making their wishes known before death.<sup>62</sup> The first alternative, collective solidarity, does not appear to be operated anywhere in the world either.<sup>63</sup> Most countries have adopted a broad opting-in<sup>64</sup> or a broad opting-out system,<sup>65</sup> although Austria operates a strict opting out system where organs can be removed without the views of close relatives being taken into account.<sup>66</sup> Some countries using an opting-out system still seek consent by relatives in practice as a matter of respect and avoiding bad publicity for organ donation.<sup>67</sup> The formulation of the law in France and Spain only allows removal to occur where no explicit or informal objection has been made by the deceased to donation at any time. This effectively means doctors have to check with relatives.<sup>68</sup>

Which system is more effective in practice? Comparing the cadaver procurement rates of countries operating an opt-out system in practice with those operating an opt-in system is fallible because of the influence of other factors such as road deaths. However, the Kings Fund Report have noted 2 countries where clear evidence of the impact of presumed consent is available,

"the evidence suggests that the introduction of presumed consent in Belgium had a significant impact on the availability of organs" and "the evidence from Singapore adds to that of Belgium as to the efficacy of presumed consent legislation."<sup>69</sup>

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<sup>62</sup>The main evidencing of such a wish is the carrying of the donor card. The number of people carrying a donor card in Western European countries and the United States varies between the small percentages of 10% and 25%. Hessing et al., *Psychological Aspects of Organ Procurement System, Organ replacement Therapy, Ethics Justice Commerce* (ed. W.Land and J.B.Dossetor) *Springer Verlag*, 1991, 287-290; R.W.Evans and D.L.Manninen, *US Public Opinion Concerning the Procurement and Distribution of Donor Organs, Trans Proc* 1988, 20(5), 781-5; H.Gabel and K.Lindskoug, *A Survey of Public Attitudes Toward Cadaveric Organ Donation in a Swedish Community, Trans Proc* 1988, 20(3), 431.

<sup>63</sup>Excepting the 'lawful' use of executed prisoners organs (e.g. in China and Iraq) and instances of illegal force in using organs.

<sup>64</sup>E.g. UK, Eire, United States and the proposed system in Holland under the Dutch Organ Donation Bill, Germany, Canada, New Zealand and Australia.

<sup>65</sup>E.g. Belgium, Norway, Sweden, Denmark, France and Spain.

<sup>66</sup>Conference of European Health Ministers (1987), *Current legislation in Council of Europe Member states and Finland and Results of European Co-operation*, Council of Europe Strasbourg.

<sup>67</sup>Countries in this position include Greece Italy and Spain.

<sup>68</sup>For the position in France see J.Hors et al., *France Transplant* in R.Matesanz et al. (eds.) *Transplant*, 4 (Produced with the Council of Europe, Paris). For the position in Spain see R.Matesanz and B.Miranda (1992) *Organizacion Nacional de Transplantes*, in *Transplant* *ibid*.

<sup>69</sup>Kings Fund Research Report, 18, 58-59.



P.Michielson suggests the Belgian legal position, where the deceased's family is granted the possibility to object in the absence of a statement of the deceased's will on the matter, has, "apparently succeeded in working out a compromise acceptable to all (In Belgium)."<sup>70</sup> However, consensus might be against adopting the Belgian position in many countries, particularly those with a strong rights tradition of rights.<sup>71</sup> G.Pennings suggests a system of "confirmed opinion and forced commitment"<sup>72</sup> could be the answer. Under this system all persons would have to register their wishes regarding disposal of their body after death, but as well as registering "yes" or "no" they could register "cannot answer the question." I have suggested elsewhere that,

"(t)his system, which would place people's choice at the heart of cadaveric donation, would probably result in increased numbers of people registering as donors, thereby improving organ harvesting."<sup>73</sup>

The improvement might come directly by simply denying relatives any right of refusal on the ethical basis that, "allowing the next-of-kin to object to a donation would come down to treating a person's altruistic desires as suspect, as something which has to be corroborated by others."<sup>74</sup> If relatives were asked, the clear evidence of the deceased's will would be a deterrent to them saying no. This system looks promising providing registration can be ensured.<sup>75</sup>

In terms of organisational factors in relation to society, Gore discovered in a 1989 audit study in the United Kingdom that a 10% potential loss in organs was sustained by failure

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<sup>70</sup>Effect of Transplantation Laws on Organ Procurement, P.Michelson, 34-39 at 39 in J.L.Touraine ed. *Organ Shortage the Solutions*, Kluwer, 1995.

<sup>71</sup>Opposition to this system ranges from 30-75% - see Kings Fund Research Report, 18 at p43. In the UK: OPCS study opposition 48%; Department of Health study 43%; British Kidney Patients Association study 30%. A study in the USA found 52% against such a system (D.S.Kittur et al., Incentives For Organ Donation? *The Lancet*, 1991, 338, 1441-1443. A Dutch study indicated 75% of people in Holland wanting to keep their present opting in system (W.Kokkedee, Kidney Procurement Policies in the Eurotransplant Region, *Social Science and Medicine*, 1992, 35(2), 177-182).

<sup>72</sup>Ch 22 in *Organ and Tissue Transplantation in the European Union: Management of Difficulties and Health Risks Linked to Donors*, Ed. Y.Englert, *Martinus Nijhoff*, 1995.

<sup>73</sup>Review of Organ and Tissue Transplantation in the European Union: Management of Difficulties and Health Risks Linked to Donors (Ed. Y.Englert, *Martinus Nijhoff*, 1995) in *IDHL*, 1996, 47(1), 126-127.

<sup>74</sup>Pennings, *Organ and Tissue Transplantation in the European Union: Management of Difficulties and Health Risks Linked to Donors*, Ed. Y.Englert, *Martinus Nijhoff*, 1995, at Ch 22.

<sup>75</sup>A parallel exists in the form of registration for political elections - most people register but gaining the same success rate for transplantation may be harder.



of doctors to approach relatives.<sup>76</sup> It is possible to address this problem (as is being attempted in the U.S.) through routine enquiry and/or required request laws and policies.

#### **2.3.3.3. Monetary Investment in Transplantation and Political Factors.**

Availability of ICU support and beds is influenced by financial factors, but beyond this, procurement in 'western bloc' countries is relatively unaffected by financial concerns. This is due to the large amounts of money spent on health care and also the specific recognition that transplantation is generally more cost effective than dialysis. However, the same position does not apply to many countries outside the 'western bloc' where money and political factors can often lead to insufficient funds to buy the required equipment / have sufficient resources.<sup>77</sup> Many 'non-western bloc' countries have rates of kidney transplantation below 10 or 15 p.m.p - partly as a result of lack of money in some cases.

#### **2.4. Conclusions.**

Better ICU arrangements, better transplant co-ordination arrangements and routine enquiry/required request arrangements and catheter NHBD where in accordance with the patient's will are likely to have a significant impact on transplantation rates in many countries. However, in most countries such methods are probably insufficient to meet demand without being combined with high levels of LDT use. Italy, Greece and most countries outside Europe have a low rate of cadaveric transplantation further amplifying the need for living donation. The alternatives to this approach (EV, Pittsburgh Protocol NHBD and a presumed consent system of procurement) are ethically objectionable and likely to get a mixed reception publicly and professionally. If nothing else, presumed consent and 'twilight zone' methods of procurement should be avoided to protect levels of public support for transplantation which are critical for overall willingness to donate.

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<sup>76</sup>S.M.Gore et al., Organ Donation From Intensive Care units in England and Wales: A two year Confidential Audit of Deaths in Intensive Care, *BMJ*, 1992, 304, 349-355. This is likely to be a problem in most countries.

<sup>77</sup>For instance, in Romania there is insufficient money to buy the machinery necessary to meet best practice in ensuring prospective living donors are in a fit and healthy state to donate. This has been a major reason behind the rare use of LDT in Romania (Personal Communication with Professor Proca, Bucharest Centre).



## **Chapter 3 General Limits to LDT Use.**

### **3.1. Introduction.**

The need to maximise use of transplantation is already clear but under what general circumstances is it ethical to use LDT?<sup>1</sup> Within the limits of LDT being supplemental to CDT the critical questions are:

1. how many organs can LDT yield?;
2. what practices are generally required to maximise yield?; *and*
3. what practices are acceptable given a combined assessment of the clinical benefits of LDT to the recipient (vis-à-vis cadaveric donation and other alternatives available), the benefits and detriments for the donor and the general impact of using living donation?

### **3.2. Possibilities for Increasing Organ Procurement Levels Using Living Donation.**

Use of LDT varies markedly between countries and even between individual centres.<sup>2</sup> Most countries have a rate around 1-2 p.m.p. both within Europe and outside of it (partially illustrated by graph 28). Some countries do no or virtually no LDT's (see graphs 30-32). In 1995 only USA, Denmark, Sweden, Holland and Switzerland had an LDT rate p.m.p exceeding 5 (see graph 26). Heavy and primary reliance on LDT has generally been confined to countries with relatively undeveloped cadaveric programmes.<sup>3</sup> However, in Norway and USA, very high LDT rates p.m.p. are sustained alongside relatively well developed cadaveric programmes - if replicated, this approach could have

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<sup>1</sup> The *primum non nocere* principle demands that LDT be used essentially as a supplement to cadaveric transplantation and only exceptionally in preference.

<sup>2</sup> See chapter 10 for breakdown of European centres.

<sup>3</sup> Turkey and Greece are potent examples.

fundamental global ramifications. Even if through various obstacles<sup>4</sup> cadaveric procurement remained low in some countries, the impact of high rates of LDT would remain pronounced. Several graphs illustrate this point:

- *Graph 38*<sup>5</sup> illustrates Norway's 1990 rate of 22.8 LDT's p.m.p. as a theoretically obtainable goal for other countries. If other major transplant countries had obtained this rate of LDT in 1995 they would all have a transplant rate of around the 40 p.m.p. mark or above. Even if this left a slight shortage in some procurement areas improvements in cadaveric procurement could realistically make up the remaining shortfall. In many procurement areas (e.g. Spain, Portugal, USA) the rate would be high enough to reduce the current waiting list. The overall status of cadaveric procurement would still require substantial improvement in many former Eastern and Central European areas, South America, India etc. in order for supply to meet demand in these countries with their 'new projected rate of LDT.'
- *Graph 39*<sup>6</sup> illustrates the increases in LDT p.m.p. in main European areas that would be sufficient to avoid increases in waiting list sizes between 1990 and 1995. Most European countries would need to increase their LDT p.m.p. by less than 10.
- *Graph 4*<sup>7</sup> illustrates how the major European countries could all have reduced their waiting lists between 1990 and 1994 by matching Norway's LDT rate p.m.p. over this period. *Graphs 6 to 13*<sup>8</sup> illustrate how individual countries would quickly eliminate their waiting list altogether by matching the Norwegian approach.
- *Graph 14*<sup>9</sup> indicates LDT strategies to a) stabilise b) reduce by 25% and c) reduce by 50% waiting lists of various European countries and the USA over a five year period (1990-1994). In most cases a rate of LDT less than 10 p.m.p suffices to maintain waiting list levels and a 25% decrease can generally be brought about by an LDT rate of less than 15 p.m.p.

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<sup>4</sup> Such as lack of finance, ethical concerns and public attitudes.

<sup>5</sup> At page 89.

<sup>6</sup> At page 90.

<sup>7</sup> At page 55.

<sup>8</sup> At pages 57-64.

<sup>9</sup> At page 65.



### 3.3. Changes Required in Transplant Practice to Extensively Increase LDT Rates P.M.P.

To some extent the rate of LDT's p.m.p. depends on public attitudes, which can only be influenced, not determined, by medical professionals. However, medical professionals can create conditions in which LDT is *likely* to be extensively utilised. The 1995 BTS Working Party Report, which surveyed UKTSSA transplant centres, found LDT usage was correlated with whether a proactive or reactive approach is taken to addressing the issue of LDT with recipients and their families.<sup>10</sup> 15 out of 31 centres with an LDT programme approached families in a prospective fashion by setting up a personal interview; about half of these followed up with an information booklet.<sup>11</sup>

Norway has the highest rate of kidney LDT's p.m.p. and its system could act as a development model. Prominent features of the Norwegian approach are:

- The acceptance of all types of tissue mismatch;<sup>12</sup>
- Not placing donors on a waiting list if a suitable live donor is willing to donate; using pre-dialysis LDT regularly so as to improve graft survival of LDT's;
- Informing the patient and his/her family of the availability of LDT as a matter of course;
- Utilising spouses to a significant extent;<sup>13</sup> *and*
- Not using a high level of cadaveric donation as a justification for lesser use of LDT when there are still high waiting lists.<sup>14</sup>

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<sup>10</sup>P.S.Veitch, Recent Initiatives From the British Transplantation Society in Living Organ Donation In The Nineties: European Medico-Legal Perspectives (ed. D.Price and H.Akveld, EUROTOLD, 1996 at 19-23).

<sup>11</sup>BTS Working Party Report, *BTS*, 1995 at p25.

<sup>12</sup>A.Jacobsen - EUROTOLD collaboration.

<sup>13</sup>Ibid.

<sup>14</sup>This justification may be being used in Belgium and Austria in some instance (Kings Fund Report p20). The Eire approach is more sound - living donation only occurs in cases of a full-house match but this narrowly defined approach was a clear response to the fact that waiting lists have been reduced to a low level and current cadaveric supply is approximately meeting demand.

### **3.4. Weighing Benefits and Detriments in LDT.**

Calculating prospective benefit and detriment in a procedure, and its alternatives, is a core part of medical practice. The complexity in LDT is that it involves two parties - it is not just a comparison of living donation, cadaveric donation and dialysis for the prospective recipient but also an evaluation of the significance of living donation for the prospective donor. For a donor, living donation involves some inevitable harm plus risks of further harm. There are also concerns relating to informed voluntary consent of the donor. Finally, aside from direct benefit and detriment to the donor and recipient, there is also the question of whether LDT has any negative impact generally such as reducing levels of cadaveric procurement and increasing levels of trade in organs.

#### **3.4.1. Benefits of LDT to the Prospective Recipient vis-à-vis Cadaveric Transplantation.**

##### **3.4.1.1. The Relative Graft Survival of Transplanted Cadaveric and Living Donor Organs.**

Statistically, graft survival results are difficult to quantify.<sup>15</sup> There are specific difficulties in making generalised comparisons between cadaveric and living donor grafts.<sup>16</sup> Despite these qualifications an approximate analysis of graft survival and specifically cadaveric graft survival vis-à-vis living donation, can be made.

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<sup>15</sup>With transplantation as a whole this is so primarily because of varying clinical hurdles for recipients (e.g. whether clinically marginal patients are accepted, the presence or otherwise of age restrictions) and for HLA matching (closeness of the match required from centre to centre and country to country varies and this will effect graft survival). There are also variations in computation of graft survival and inaccuracies in recording it (see P.K.Donnelly et al. Transplants From Living Donors in the United Kingdom and Ireland: A Centre Survey. *BMJ*, 1989, 298, 490-493).

<sup>16</sup>*Firstly* there is no uniform centre approach as regards HLA matching for LDT. Match requirements tend to be stricter than those used for cadaveric transplantation. Better graft survival results will obviously somewhat mirror increases in selectivity of use in HLA matching terms. The number of centres attaching strong importance to HLA is clearly increasing while the number attaching no or little importance is decreasing and is now a fairly small minority (F.P.Brunner et al. Combined Report on Regular Dialysis and Transplantation in Europe, 1988. *Nephrol Dial Transplant*, 1989, 4 (supp 4), 5-29). *Secondly* general conditions under which living donation is considered. For instance the stage at which living donation is used is clearly influential, pre-dialysis LDT being the 'gold standard' method of transplantation



Extensive study by D.E.R.Sutherland et al. in the US suggests that LDT produces better results than cadaveric.<sup>17</sup> This conclusion is supported by research in Norway<sup>18</sup> and indeed by most clinicians.<sup>19</sup> Often the graft superiority of LDT is considerable and acts as a counterbalancing factor when considering harm caused to the living donor.<sup>20</sup>

Reasons for LDT producing better results include: More freedom in choice in timing of the operation, allowing for better planning with better work-up and better timing of the operation for the recipient; the probability of better HLA matches with LDT, the significance of this factor depending on the choices of living donor available and the degree of selectivity used in choosing living donors; better quality matches benefiting recipient health by lessening drug levels;<sup>21</sup> (usually) decreased time in hospital and on dialysis<sup>22</sup> which may produce graft survival benefits via improved quality of life;<sup>23</sup> the possibility of immunising the future recipient with the future donor's blood; and, finally, the likely good health of living donors leading to better organs on average than those from cadaveric donors (although this depends on stringency of selection in LDT and CDT).

Data concerning comparisons of LDT and cadaveric transplantation of other organs is inevitably limited by the fact that such procedures are relatively rare. LDT liver

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(P.K.Donnely, Pre-Dialysis Living Donor Renal Transplantation - Is it Still the Gold Standard for Cost, Convenience and Graft Survival? *Trans Proc*, 1995, 27(1)).

<sup>17</sup>*Trans Proc* 1985, 17, 1503 and *Trans Proc* 1985, 17, 110.

<sup>18</sup>A.Jakobsen, Living Renal Donors - The Norwegian Experience, paper presented at the Warsaw conference, publication forthcoming in Transplantation Proceedings.

<sup>19</sup>Spital et al., The Living Kidney Donor: Alive and Well. *Arch Intern Med*, 1986, 146 at 1993; W.Bay & L.Herbert, The Living Donor in Kidney Transplantation, *Annals Intern Med*, 1987, 106, 719; H.Wilms, Indication for Living Donation in Kidney Transplants, *Trans Proc*, 1988, 20, 797; V.Bonomini, Ethical Aspects of Living Donation, *Trans Proc*, 1991, 23, 2497; A.Jacobsen, A Second Opinion In Defence of Living Donor Transplant, *Health Policy*, 1990, 16, 123-126.

<sup>20</sup>See also R.Gabriel, A Patient's Guide to Dialysis and Transplantation (4th Ed 1990) where results are presented with living donor graft survival at around 77% after 10 years as distinct from around 58% for cadaveric.

<sup>21</sup>Canadian Transplant Study Group, *Am J Kidney Dis*, 1985, 5, 328-332.

<sup>22</sup>E.R.Maher et al., Mortality and Morbidity of Long Term Haemodialysis, *Lancet*, 1987, i, 452-453.

<sup>23</sup>Such as less stress and financial hardship see N.G.Kutner et al., End Stage Renal Disease Treatment Modality and Patient Quality of Life, *Am J Nephrol*, 1986, 6, 396-402.



donation has similar results to cadaveric liver donation. The justification for using it is founded more on clinical need than results; there is a chronic shortage of transplantable livers.<sup>24</sup> Shortage of paediatric livers is particularly acute and living donation of a lobe of liver is usually from an adult to a child.<sup>25</sup> The main risks to the recipient of a liver segment are connected with the implantation procedure, but when transplanted into a child the lobes grow with the child. Statistics on long term risks are not available but there is little indication that there will be significant problems. Living donation of other organs is less established but preliminary comments can be made. LDT small-bowel segment donation is experimental and so is its cadaveric counterpart.<sup>26</sup> Living donor pancreas segment donation is extremely rare partly due to the fact that there is no shortage of available cadaveric pancreases, and also because of the serious risks involved. Living donor lung lobe donation has had reasonable results so far.<sup>27</sup>

#### **3.4.1.2. Relative Graft Survival of Cadaveric vis-à-vis LDT With Specific Kinds of Donor.**

In nearly all countries the primary LDT source is from within the close genetic family.<sup>28</sup> The major source is parent to child donation, the next is sibling donation and in a very small number of cases donations occur from child to parent. However, since the 1960's, a significant minority of donations have been between genetically unrelated pairs.<sup>29</sup>

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<sup>24</sup>See for example C.E.Broelsch et al., Liver Transplantation Including the Concept of Reduced Size Liver Transplants in Children. *Ann Surg*, 1988, 208(4), 410-420; S.Raja et al., Liver Transplant From Live Donors *Lancet*, 1989, ii, 497.

<sup>25</sup>The University of Chicago estimates that it will do 50% of its paediatric transplantations using this method. Donation generally allows the donor's liver to carry on functioning (approximately regenerating to its previous structure) while the recipient usually as a small child could only physically accommodate a small amount of liver and is particularly unlikely to get a small liver from a cadaver.

<sup>26</sup>Graft survival for both modalities is not yet clear.

<sup>27</sup>L.R.Shaw et al., quotes graft survival rates at 65% for one year and 53% at 3 year (see *The Lancet*, 1991, 338, 678-681). ULTRA allowed a friend living lung lobe donation in 1996 (reported by David Price after meeting Bob Pilling, Chair of ULTRA, in 1996).

<sup>28</sup>This might not be the case in countries where rewarded gifting and rampant commercialisation of organs occurs on a large scale, such as India, since these are done by emotionally and genetically unrelated donors.

<sup>29</sup>H.H.Sadler et al., *Semin*, 1971, 3, 86.



Besides questions of commerce and voluntariness<sup>30</sup> use of different classes of donor raises graft survival issues. The view that unrelated donors are per se inferior is unjustified. A study by B.A.Elick et al. has suggested that distant related and unrelated donors produce similar graft survival to HLA mismatched close relatives.<sup>31</sup> R.J.Ploeg et al. recently surveyed 990 living donors. Results indicated that living unrelated donors had a far better graft survival after 4 years (85%) than either mismatched relative donation (70%) or cadaveric donation (75%), with a rate very similar to haploidentical living related donors (86%).<sup>32</sup> Terasaki established similar results over 3 years, finding that spousal donation was considerably superior to cadaveric donation and slightly better than parental donation.<sup>33</sup> Alfani et al., recently reported a 12 year experience of 153 living unrelated donors at their centre in Rome which concluded there were no significant differences in using living related and living unrelated, with the latter even being superior to cadaveric grafts with ischemia less than 3 hours.<sup>34</sup> Norway has used spouses extensively and has reported good results, as well as noting the advantage of the likely close affinity between donor and recipient.<sup>35</sup> The usage criteria were that the spouse was the best available living related donor and that the patient preferred this alternative to remaining on the waiting list. Norway has also used mismatched donors with reasonable success.<sup>36</sup>

Studies do not really prove that unrelated donation is superior to other forms of donation since a higher degree of selectivity may have been used. Clearly what matters is not

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<sup>30</sup>See chapters 6 and 7.

<sup>31</sup>*Trans Proc*, 1990, 22, 343-344. P.Berloto et al.'s study of 140 related and 74 unrelated donors and found the latter to have better graft survival (*Trans Proc*, 1991, 23, 912-913).

<sup>32</sup>R.J.Ploeg et al., Living Unrelated Kidney Donation: An Under-utilised Resource? *Trans Proc*, 1993, 25(1), 1532-4 at 1533.

<sup>33</sup>P.I.Terasaki et al., High Survival rates of Kidney Transplants From Spousal and Living Unrelated Donors, *New Eng J Med*, 1995, 333(6), 333-336.

<sup>34</sup>Living Unrelated Kidney Transplantation: A 12-Year Single Centre Experience, *Trans Proc*, 1997, 29, 191-194 at 193.

<sup>35</sup>D.Albrechtsen et al., *Trans Proc*, 1990, 22, 1435. This paper indicates that since 1985 Norway procures around 6% of its total supply from spousal donation. See more recently A.Jacobsen, Living Donor Practices and Processes in Europe in D.Price and H.Akveld (ed.), *Living Organ Donation in the Nineties: European Medico-Legal Perspectives*, *EUROTOLD*, 1996, 1-12.

<sup>36</sup>Jacobsen *ibid*.

donor source but the quality of the match and other clinical factors<sup>37</sup> at hand in the individual situation.<sup>38</sup> There is a prima facie case (subject to ethical issues) to use spouses and other unrelated donors extensively at least within the limits of choosing LDT's comparable to average CDT's. In nearly all countries large scale expansion of LDT is feasible without resorting to mismatched living donors - i.e. living donors likely to have a graft survival inferior to the average cadaveric match.

### **3.4.2. Detriment and Benefit to the Donor.**

#### **3.4.2.1. Detriment in Living Donor Kidney Transplantation.**

Aside from a small amount of inevitable detriment (such as pain and scarring to the wound site) living donor kidney transplantation has a number of risks to the donor including risks of having an operation in itself (e.g. approximately 1/4000 risk of death<sup>39</sup>) and risks related to nephrectomy and living with one kidney. The risks can be grouped into risks of mortality, risks of morbidity and long term complications and risks.

#### **Risk of Mortality.**

It is not always easy to discern whether deaths are caused by donation or by other independent factors, additionally, not all donor deaths are reported. A methodical and consistent world-wide method of reporting donor death would be beneficial. EUROTOLD's donor health registry, which has limited data because it only started in 1996, provides a confidential method for European transplant centres to provide data on

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<sup>37</sup>Such as age matching of donor and recipient (see e.g. P.K.Donnelly et al., Matching For Age in Renal Transplantation, *New Engl J Med*, 1990, 322(12), 851-852.) and age of the donor (However, Kostakis et al., *Trans Proc*, 1990, 22, 1432-1433, found that there was no statistical difference for graft survival with recipients whose donors were over 60 than those who were under. What would appear to matter more than age per se is health screening of donors to a sound standard).

<sup>38</sup>Gaber et al. *Trans Proc*, 1990, 22, 340-341.

<sup>39</sup>R.A.Sells, Voluntarism and Informed Consent in Systems of Donor Recruitment ed. De Charro et al., *Kluwer*, 1992, 87.



mortality incidences and might ultimately be utilised world-wide. Whilst data is being gathered estimations of mortality must suffice.

A number of studies estimate the risk of mortality to be around 0.1%.<sup>40</sup> Studies specific to the US tend to report a mortality rate of less than 0.1% and nearer 0.03%.<sup>41</sup> In many studies it is 0%.<sup>42</sup> In general terms, the risk to the donor can probably be summed up as minimal<sup>43</sup> or very low.<sup>44</sup> Although living donor nephrectomy has become a routine procedure it's complexity is likely to mean risks are slightly increased in centres that have little experience.

### Risks of Morbidity.

The incidence of serious postoperative morbidity can be assessed as low; within the range of 1-3%<sup>45</sup> although a few studies have reported higher<sup>46</sup> and lower<sup>47</sup> rates. The

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<sup>40</sup>See W.J.Bay et al., The Living Donor in Kidney Transplantation, *Ann Intern Med*, 1987, 106, 719-727 reviewing 16 studies from around the world and identifying 3 deaths from 2495 donors. See also Bonomini et al., Is Living Donation Still Justifiable, *Neph Dial Trans*, 1990, 5, 407-409.

<sup>41</sup>J.S.Najarian et al., 20 Years or More of Follow-up of Living Kidney Donors, *The Lancet*, 1992, 340 at 807.

<sup>42</sup>For instance the Oslo experience (Jakobsen, personal communication 1996) see also University of Wisconsin Medical School (M.J.Waples et al., Living Donor Nephrectomy: A 20 Year Experience, *Urology*, 1995, 45(2), 207-210). A study of 681 donors over a 20 year period). Spital et al.'s mid nineteen eighties study of US transplant centres had 79 out of 83 responding centres answer a question about donor mortality 94% of which had not experienced a donor death (A.Spital et al., The Living Kidney Donor, *Arch Intern Med*, 1986, 1993, See also M.D.Smith et al., Study of 9 U.S. Centres (536 donors over 12 years), *Am J Kid Dis*, 1986, 8(4), 223-233. .

<sup>43</sup>E.g. Williams et al., *Ann Intern Med*, 1986, 105, 1; Talseth et al., *Kidney Int*, 1986, 29, 1072. W.J.Bay et al., The Living Donor in Kidney Transplantation, *Ann Intern Med*, 1987, 106, 719-727.

<sup>44</sup>J.S.Najarian et al., 20 Years or More of Follow-up of Living Kidney Donors, *The Lancet*, 1992, 340 at 807, Survey of all members of the American Society of Transplant Surgeons discovering 17 postoperative deaths over a period of 20 years in the USA and Canada. The figure of 0.03% is derived from a study of 19368 living related donor nephrectomies between January 1980 and January 1991. The major cause of death was pulmonary emboli.

<sup>45</sup>Such as R.M.R. Taylor et al., Renal Transplantation in the United Kingdom and Ireland- The Centre Effect, *The Lancet*, 1985, i, 798-802; T.Sherwood et al., Renal Angiography Problems in Live Donors, *Br J Radiol* 1978, 51, 99-105; Levey et al., Kidney Transplantation From Unrelated Living Donors, *New Eng J Med* 1986, 314, 914; D.A.Ogden. Consequences of Renal Donation in Man, *Am J Kidney Dis*, 1983, 2, 501-511.

<sup>46</sup>E.g. J.F.Dunn, Living Related Kidney Donors: A 14 Year Experience, *Ann Surg*, 1986, 203, 637-643 (7%) see also M.J.Waples et al., Living Donor Nephrectomy: A 20 Year Experience, *Urology*, 1995, 45(2), 207-210 (17%).



incidence of simple complications (e.g. infection of the wound site) is within the 15-30% range in most studies.<sup>48</sup> Taking minor and major complications over a range of studies Tilney and Kirkman have found complications rates within the range of 15-47%.<sup>49</sup> Wide variations in rates of complication between different studies may partly be due to different ideas about what constitutes a complication. It is also influenced by the degree of rigour applied to follow-up; many studies focus on the more immediate postoperative period when some complications may not become apparent until later.<sup>50</sup> While patients are likely to come back to the transplant centre in the event of a serious complication they may be commonly failing to do so in the event of more minor complications which may result in serious under-reporting of such complications as a result. It is to be hoped that EUROTOLD's donor health registry will encourage a trend towards systematic annual follow-up of all donors.

#### Long Term Complications and Risks.

Possible longer term risks of donation include hypertension, proteinuria and progressive failure of the remaining kidney. Some studies have found that kidney donation poses no risk with regard to these conditions.<sup>51</sup> However, other studies have identified one or more of these conditions as material risks in donation.<sup>52</sup>

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<sup>47</sup>E.g. T.Yasamura et al., Experience with 246 Living Related Donor Nephrectomy Cases at a Single Institution in Japan, *Jpn J Surg*, 1988, 18, 252-258.

<sup>48</sup>Sollinger et al., *Transplantation*, 1984, 38, 664-668. M.Hoette et al. *Kidney Int*, 1986, 29, 430; P.Berloto, *Trans Proc*, 1985, 17(2), 13-17. R.Simmons, *Trans Proc*, 1977, 9, 143 reports 28.2% from an extensive 1974 University of Minnesota study. More recently Weiland has reported the University experience as 17% (1984)

<sup>49</sup>Consideration of Kidney Donation Using Living Related Sources, *Transplantation and Clinical Immunology*, 1985, 16, 207-213.

<sup>50</sup>E.g. depression, pain and discomfort at the wound site, chronic urinary infection, incisional hernia.

<sup>51</sup>E.g. G.M.Beekman et al., Analysis of Donor selection procedure in 139 Living Related Kidney Donors and Follow-up Results For Donors and Recipients, *Nephrol Dial Transplant*, 1994, 9, 163-8; C.F.Anderson et al., The Risks of Unilateral Nephrectomy: Status of Kidney Donors 10-20 Years Postoperatively, *Mayo Clin Proc*, 1985, 60, 367-374; F.Vincenti et al., Long Term Renal Function in Kidney Donors, Sustained Compensatory Hyperfiltration With No Adverse Effects, *Transplantation*, 1983, 36, 626; D.Weiland et al., *Trans Proc*, 1984, 16, 5-7; S.L.Williams et al., Long Term Renal Function in Kidney Donors: A Comparison of Donors and Their Siblings, *Ann Intern Med*, 1986, 105, 1-8; J.S.Najarian et al., 1992 *ibid*; P.M.Ter Wee et al., Pair Tested Renal Reserve Filtration Capacity in Kidney Recipients and Their Donors, *JASN*, 1994, 4, 1798-1808; I.J.Miller et al., Impact of Renal Donation, Long Term Clinical and Biochemical Follow-Up of Living Donors in a Single Centre, *Am J*



Despite differing findings the evidence increasingly points to the absence of significant long term risks. Some reports show LDT does not have serious clinical effects on the donor after 20 years<sup>53</sup> and even 25 years or more.<sup>54</sup> Najarian's recent study involving follow-up from 21-29 years (average 23) concludes that, "renal transplant donors are not at increased risk for development of renal failure" and that other risks are low.<sup>55</sup> Most importantly Kasiske et al., have conducted a substantial review of 48 studies with 3124 patients and 1703 controls using multiple linear regression to combine studies and adjust for differences in the duration of follow-up, the reason for reduced renal mass, the type of controls, age and gender.<sup>56</sup> The authors pointed out that differences in the results of previous studies may have been due to,

"differences in the amount of renal mass removed, age at the time of renal mass reduction, unsuspected renal damage to the remaining kidney, or other factors. In addition the relatively small numbers of patients in most studies and the use of different controls have made the interpretation of results difficult."<sup>57</sup>

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*Med*, 1985, 79, 201-208; P-L.Liu et al., Renal Function in Unilateral Nephrectomy Subjects, *J.Urol* 1992, 147, 337-9; C.Bustza et al., Pregnancy After Donor Nephrectomy, *Transplantation* 1985, 40, 651-654. T.Talseth et al., Long Term Blood Pressure and Renal Function in Kidney Donors, *Kidney Int*, 1986, 29, 1072-1076 reported a moderate increase in blood pressure in Norwegian donors and 15% were hypertensive. However the report concluded that donor nephrectomy represents no long term health risk. For a fuller review of findings of studies in this area see B.L.Kasiske et al., Long-Term Effects of Reduced Renal Mass in Humans, *Kidney Int*, 1995, 48, 814-819.

<sup>52</sup>E.g. R.B.Colvin et al., *Lab Invest*, 1982, 46, 275-281; R.M.Hakim et al., *ibid*; V.Lent et al., Nephropathy in Remnant Kidneys: Pathological Proteinuria After Unilateral Nephrectomy, *J Urol*, 1994, 152, 312-6. However the presence of risk factors may not correlate with decreased renal function, for instance increases in hypertension tend only to match those occurring in the general population and increases in proteinuria tend not to result in glomerulosclerosis at least in the medium term. For a fuller review of studies on long term consequences see B.L.Kasiske et al., Long-Term Effects of Reduced Renal Mass in Humans, *Kidney Int*, 1995, 48, 814-819.

<sup>53</sup>Such as Vincenti et al., *Transplantation*, 1983, 36, 626; R.M.Hakim et al., *Kidney Int*, 1984, 25, 930; J.A.Velosa et al., *Trans Proc*, 1985, 17, 100.

<sup>54</sup>E.g. W.J.Bay et al., Prognosis After Donor Nephrectomy: An Update, *Int J Art Org*, 1987, 10, 9-13 also J.S.Najarian et al., 20 Years or More of Follow-up of Living Kidney Donors, *The Lancet*, 1992, 340, 807-810.

<sup>55</sup>J.S.Najarian et al., 20 Years or More of Follow-up of Living Kidney Donors, *The Lancet* 1992, 340, 807-810 at 809.

<sup>56</sup>B.L.Kasiske et al., Long-Term Effects of Reduced Renal Mass in Humans, *Kidney Int*, 1995, 48, 814-819.

<sup>57</sup>*Ibid* at p814.

To address this they carried out a meta-analysis; testing if reduction in renal mass leads to progressive changes in any of proteinuria, hypertension and/or renal function in humans. The conclusion was that the reductions in renal mass did not have any of these consequences. Some increases of proteinuria were detected following uninephrectomy but these did not progress during the period of follow-up while increases in blood pressure were sufficiently low not to cause an increased incidence in hypertension. The considerable weight of this study in combination with other recent results is probably enough to assert that mid to long-term risks of nephrectomy are minimal or non-existent.

There are no donor studies on 30-40 year risks. Some animal experiments point toward the possibility of significant very long term risks.<sup>58</sup> However, D.M.Narkun-Burgess et al.,<sup>59</sup> comparing 62 US soldiers who lost one kidney during the Second World War and were followed up for 45 years after uninephrectomy with 620 controls found they showed no increases in mortality, prevalence of hypertension and renal dysfunction which could be related to the previous loss of a kidney. However, this study may contain inherent bias in so far as the soldiers are likely to have been a more healthy sub-group than the control sample and more data is needed to firmly assess very long term risks in donation.

#### **3.4.2.2. Detriment With Non-Renal Organ LDT.**

##### **Liver LDT.**

Experience of liver LDT is very limited, both in terms of the numbers of such transplants and the fact that the procedure only started to be utilised in the late 1980's.<sup>60</sup>

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<sup>58</sup>"Reliable long term and large scale studies of medical records are lacking....This is a serious deficiency because animal experiments have demonstrated that adverse outcomes resulted after nephrectomy in rats after 40% of normal life span, which would point to adverse outcomes in humans after approximately 30 years" (F.Th.De Charro et al., Donor Recruitment in Europe, in De Charro et al. (ed), Systems of Donor Recruitment, *Kluwer*, 1992 at 10). See also A.Chanutin et al., Experimental Renal Insufficiency Produced By Partial Nephrectomy, *Arch Intern Med*, 1982, 49, 767-787 and T.H.Hostetter et al., Hyperfiltration in Remnant Nephrons: A Potentially Adverse Response to Renal Ablation, *Am J Physiol*, 1981, 241, F85-F93.

<sup>59</sup>Forty-five Year Follow-up After Uniphrectomy, *Kidney Int*, 1993, 43, 1110-1115.

<sup>60</sup>S.Raia et al., *Lancet*, 1989, 26, 497.



Obviously there is no donor data relating to long term risks. There is experience of livers being reduced in people with problematical liver conditions and this suggests that risk to a liver donor should be low.<sup>61</sup> Some early studies suggested comparable risks to those kidney donation<sup>62</sup> and some recent series have reported no serious complications from donation.<sup>63</sup> However, R.W.Busuttil pointed out higher risks were consistent with the complexity of the segment removal procedure<sup>64</sup> and found early complications to include incidental splenectomy, bile leak, subphrenic collection and wound infection.<sup>65</sup>

### LDT Lung Lobe.

Living donor lung lobe donation carries the risk of lobectomy.<sup>66</sup> This has been estimated as 1.3.% for patients under 60 who undergo lobectomy because of lung cancer<sup>67</sup> but is likely to be less than 1% for a donor coming into the procedure with good health (as opposed to being a smoker and/or having other problems). Long term risks from lobectomy are unknown - a possible impact would be reduced pulmonary function. There is a question of whether this level of risk and uncertainty is acceptable at all, if it is the justification must surely be high. Shaw et al., have suggested the justification would be to select patients for whom a cadaveric organ is unlikely to become available, are likely to deteriorate but are sufficiently healthy and agree to participate in rehabilitation programmes and refrain from smoking.<sup>68</sup>

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<sup>61</sup>P83 *ibid.*

<sup>62</sup>E.g. P.A.Singer et al., *New Engl J Med*, 1990, 321, 620.

<sup>63</sup>M.Haberal et al., experience of 15 donors at Baskent University Hospital, Turkey (Living Donor Transplantation: Single Centre Experience, *Trans Proc*, 1996, 28(1), 65-7).

<sup>64</sup>Living Related Liver Donation: CON, *Trans Proc*, 1991, 23(1), 43-5.

<sup>65</sup>*Ibid.*

<sup>66</sup>L.R.Shaw et al., *The Lancet*, 1991, 338, 678-681.

<sup>67</sup>R.J.Ginsberg et al., Modern Thirty Day Operative Mortality for Surgical Resections in Lung Cancer, *J Thorac Cardiovascul Surg*, 1983, 86, 654-58.

<sup>68</sup>L.R.Shaw et al., *The Lancet*, 1991, 338, 678-681 at 679.

### Other Organ LDT.

Living donor heart and living donor cornea donation are ordinarily only incidental to a therapeutically necessary removal (i.e. the donor as a patient - domino transplant). This is not quite the same as living donation in the true, ordinary sense and presents issues which are better discussed elsewhere.<sup>69</sup> Outside of therapeutically necessary removal both forms of donation unacceptable levels of detriment. The practice of trade in corneas, which is common in some countries including India, is ethically indefensible - leading as it does to an overall health detriment to the donor-recipient pair.<sup>70</sup>

LDT pancreatic vessel length donation presents risks of splenectomy and treatment for infection and loss of endocrine and exocrine function. The risks appear to be more serious than liver segment, lung lobe and kidney, donation and may not be within an acceptable level.<sup>71</sup> The actual detriment and risks in small bowel segment donation, on the other hand, appear to be limited and acceptable.<sup>72</sup>

#### **3.4.2.3. Detriment and Voluntary Informed Consent.**

If a clinician is utilising a living donor the fact that the donor is taking risks should make the clinicians communication about these risks and the process of donation of the utmost importance. The neutrality of the environment for decision-making and the informedness and voluntariness of the decision made by the prospective donor are critical to justifying donation as a bona-fide expression of autonomous decision-making. The question is whether living donation can ever be conducted in this environment in practice. This is a critical issue examined in the following 4 chapters particularly chapter 6. For

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<sup>69</sup>Because they are more akin to general issues involving patients than to those involving donors.

<sup>70</sup>It involves an exchange of site from one person to another when the optimum optical solution would simply have been to keep things as they were.

<sup>71</sup>D.E.R.Sutherland et al., Medical Risks and Benefit of Pancreas Transplants From Living Related Donors in Land and Dossetor, *Organ Replacement Therapy: Ethics, Justice and Commerce*, Springer Verlag, 92-101.

<sup>72</sup>E.Deltz, Medical Risk and Benefit in Small-Bowel Segment Donors in Land and Dossetor (eds.), *Organ Replacement Therapy: Ethics, Justice and Commerce*, Springer Verlag, 110-116.



now it can only be stated that a carefully organised system of securing donor consent may be able to prevent most problems.

#### **3.4.2.4. Benefits to the Donor in Organ LDT.**

The assertion that donating an organ is often psychologically beneficial is supported by questionnaire and interview studies conducted with living donors. Fellner and Marshall's 12 donor study found that the donation had a consistently positive long lasting impact on the donor's life.<sup>73</sup> R.G.Simmons, S.D.Klein and R.L.Simmons conducted a one year follow-up study of living donors and concluded that donation was typically an exceedingly positive experience for the donors.<sup>74</sup> This result was confirmed in a 5-9 years post-transplant study by Simmons and Anderson which found donors had higher self-esteem, positive changes in depressive affect and increased family closeness.<sup>75</sup> Eisendrath's study also concluded that donation tends to have a positive impact on the lives of donors.<sup>76</sup> Bunzendahl et al., found a neutral evaluation by 83 donors of their general quality of life after donation, but with positive improvements in self-esteem for the majority of donors.<sup>77</sup> Westlie et al's quality of life study of 494 Norwegian donors (up to 19 years post-donation) found that they scored better than controls on 13 out of 19 quality of life indicators (6 out of 10 on psychological aspects).<sup>78</sup>

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<sup>73</sup>C.H.Fellner, J.R.Marshall, Twelve Kidney Donors, *J.Am.Med.Assoc*, 1968, 206, 2703-2707 and Kidney Donors Revisited, *Am J Psychiatry*, 1977, 134, 575-576.

<sup>74</sup>R.G.Simmons, S.D.Klein, R.L.Simmons, *The Gift of Life: The Social and Psychological Impact of Organ Transplantation*, John Wiley & Sons, 1977.

<sup>75</sup>R.G.Simmons, C.R.Anderson, Social-Psychological Problems in Living Donor Transplantation, in J.L.Touraine et al., (ed), *Transplantation and Clinical Immunology XVI*, Elsevier Science Publishers, 1983, 47-57.

<sup>76</sup>R.M.Eisendrath, Psychologic Considerations in the Selection of Kidney Transplant Donors, *Surg Gynec Obstet*, 1969, 129, 243-248. See also, The Role of Grief and Fear in The Death of Kidney Transplant Patients, *Am J Psychiatry*, 1969, 126, 381.

<sup>77</sup>Retrospective Evaluation of Psychosocial Factors in Former Living Related Kidney Donors in Organ Replacement Therapy: Ethics, Justice and Commerce, (ed. Land and Dossetor, *Springer Verlag*, 1991 at p57). Similarly improvements in self esteem had been found in Sadler et al's study (in *The Gift of Life: The Social and Psychological Impact of Organ Transplantation*, John Wiley & Sons, 1977, p502).

<sup>78</sup>Quality of life in Norwegian Kidney Donors, *Nephrol Dial Transplant*, 1993, 8, 1146-1150.

The above studies paint a positive picture of donation, but there can be problems. R.G.Simmons et al.'s study had also reported that the benefits might "have been less evident if the questionnaire were administered in a situation unrelated to donation." They added that "(d)espite this benign picture for the majority of donors, at all points in time there appeared to be a small group of donors who were extremely ambivalent or regretful of their decision (5% - 8%)"<sup>79</sup> Westlie et al's. study of Norwegian donors revealed 94% of donors expressing that they would probably or definitely donate again with a low percentage (1.4%) saying they definitely would not.<sup>80</sup>

The findings of psychological / psychiatric trauma in donation are quite considerable. Morris et al. evaluated the quality of life of 12 donors 9 - 23 months after donation. The main questionnaire focused on both the donors relationship with the recipient and the experience of donation. A general health questionnaire was also used.<sup>81</sup> In 4 out of 12 donors significant psychiatric morbidity was found. Hirvas et al., conducted a study of 68 donors 6 months and then 6 years after donation.<sup>82</sup> The donors were interviewed by a psychiatrist and a Rorschach test was performed. 24 donors experienced mild trauma while a further 12 had experienced moderate to severe trauma.

There has been specific analysis of depression in some studies. In a 1966 study, Kemph found unconscious resentment by donors to recipients and moderate depression in all the donors studied.<sup>83</sup> Kemph's view that donor's giving 'something for nothing' could predispose them to post-operative depression was supported by W.Cramond et al. in this early period.<sup>84</sup> However, later studies have not found incidence of depression higher

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<sup>79</sup>The Gift of Life: The Social and Psychological Impact of Organ Transplantation, *John Wiley & Sons*, 1977 at 431-3.

<sup>80</sup>L.Westlie et al., Quality of life in Norwegian Kidney Donors, *Nephrol Dial Transplant*, 1993, 8, 1146-1150.

<sup>81</sup>Morris P, St George B et al., Psychosocial Complications in Living Related Kidney Donors: An Australian Experience, *Trans Proc*, 1987, 19, 2840-2844.

<sup>82</sup>Hirvas J, Enckell M et al., Psychological and Social Problems Encountered in Active Treatment of Chronic Uraemia, *Acta Med Scand*, 1976, 200, 17-20.

<sup>83</sup>See J.P.Kemph, Renal Failure, Artificial Kidney and Kidney Transplant, *Am J Psychiatry*, 1966, 122, 1270-4.

<sup>84</sup>See W.Cramond et al., Psychological Screening of Potential Donors in a Renal Homotransplantation Programme, *Brit J of Psychiatry*, 1967, 113, 1213-1221.



than in the general population.<sup>85</sup> Indeed, in 1985, Simmons and Anderson analysed the combined effect of large scale donor studies (N=1460, 1501, 2460) and their controls finding that they had similar pre-donation measures of depressive effect but that the donors had considerably 'better' (less depressed) measures both 1 year and 5-9 years after donation.<sup>86</sup> In addition, Simmons and Bernstein have found depression to be rare in adolescent kidney donors.<sup>87</sup>

It must also be concluded at this stage that there is no positive correlation between donation and depression. However, studies do indicate some relationship between a person's experience of donation/attitude towards it and the success of the graft outcome in the recipient. Simmons and Karnstra-Hennen studied 147 living related donors between 1970-1973 who received survey interviews pre-transplant.<sup>88</sup> At the time the article was written 47 of the donors had corresponding recipients who had 'lost' the donated kidney. The authors were able to interview 30 of these donors.<sup>89</sup> 84% of 141 donors interviewed post-transplant would have done the same again had the clock been turned back. However, the response appeared to be related to graft outcome. 17% of donors whose recipients grafts had failed indicated feelings of regret whereas only 3% of the other donors did so.<sup>90</sup> Other studies have confirmed the connection between increased levels of regret post-donation and graft failure. The 94% of donors who would probably or definitely donate again in Westlie's study was compared to 89.2% in the sub-group of donors whose recipients had died, with higher numbers in the second cohort definitely not wanting to donate again (1.4% as against 4.3%). However Westlie et al's study also indicated that the sub group of donors whose recipients grafts had failed

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<sup>85</sup>E.g. C.H.Fellner and J.R.Marshall, Twelve Kidney Donors, *JAMA*, 1968, 206, 2703. Simmons and Karnstra-Hennen below. See also Simmons and Anderson above indicating that donors scored lower on depressive effect than did members of their family who could have volunteered to donate but did not do so.

<sup>86</sup>60% and 49% of donors respectively at these two times having better results than the controls.

<sup>87</sup>Bernstein and Simmons, The Adolescent Kidney Donor: The Right to Give, *Am J Psychiat*, 1974, 131, 1338.

<sup>88</sup>Simmons and Karnstra-Hennen, The Living-Related Kidney Donor: Psychological Reactions When the Kidney Fails, *Dialysis and Transplantation*, 8(6), June 1979.

<sup>89</sup>16 corresponding recipients were dead, 6 on dialysis and 6 had new functioning grafts.

<sup>90</sup>Problems for donors in the survey as a whole were focused around a wide range of issues.

still scored as highly as the control group on quality of life factors.<sup>91</sup> Bunzendahl et al's study of 83 donors in Hannover, Germany found that 89.7% of donors with successful recipient grafting would donate again if the clock was turned back as against 84% for those without successful recipient graft survival.<sup>92</sup>

In all but exceptional cases (most of which could be screened out before donation) donation appear not to be an act of psychopathology unless one takes the view that transplantation as a whole is maleficent (and hence psycho-pathological to be involved in). Incidences of psychological and psychiatric morbidity can also be offset against the enrichment that can occur from donation. One danger, examined further in chapter 6 is that the act of service is used by the prospective donor as a screen with which to hide ambiguous feelings and motivation for donation - outright or circumstantial pressures may encourage a donor to deny his/her true feelings about donation, particularly if they are against the act of donation. The results of studies suggesting that donation can have a positive impact (on self-esteem etc.) may be distorted through the donors lens of not wanting to experience cognitive dissonance in relation to the act of donation. Nevertheless it is difficult to dispute that the act of donation has positive psychological benefits in many cases and is in some cases simply a noble act designed to benefit another - perhaps, as Simmons suggests,

"the skepticism with which altruistic acts are regarded in the literature should be re-examined."<sup>93</sup>

Clearly, also, some account must be taken of the fact that not donating could under certain circumstances cause psychological detriment - both through negative feeling about having missed an opportunity to be of service to another and, more potently, in

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<sup>91</sup>L. Westlie et al., Quality of life in Norwegian Kidney Donors, *Nephrol Dial Transplant*, 1993, 8, 1146-1150.

<sup>92</sup>Retrospective Evaluation of Psychosocial Factors in Former Living Related Kidney Donors in Organ Replacement Therapy: Ethics, Justice and Commerce, (ed. Land and Dossetor, *Springer Verlag*, 1991 at p57).

<sup>93</sup>Gift of Life, Wiley and Sons, 1977 at 445.



occasional cases where the act of donation by the prospective donor is essential to preserve the well-being of a person whom the prospective donor has a critical relationship to.

### **3.4.3. General Impact of Donation**

#### **3.4.3.1. The Impact of Increasing LDT on Cadaveric Supply.**

Strong cadaveric procurement has sometimes led to lower LDT rates.<sup>94</sup> However the USA has fairly good cadaveric procurement but still has a significant rate of living donation (see graph 1). Some countries having average / lower cadaveric procurement still only have a low LDT rate.<sup>95</sup> The real question, however is whether use of LDT can adversely impact on cadaveric procurement. Although problems in cadaveric procurement are an incentive for the development of a strong living donor programme<sup>96</sup> LDT is unlikely to influence the rate of cadaveric donation<sup>97</sup> except in cases where an established LDT programme acts as a disincentive to facing resistance to development of a cadaver programme.<sup>98</sup> This is a problem of organisational motivation to reduce waiting lists, not an intrinsic consequence of using LDT.<sup>99</sup>

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<sup>94</sup>Belgium, Austria, Spain, Portugal.

<sup>95</sup>Canada, Australia, UK

<sup>96</sup>E.g. Norway (see Graph 5), Turkey, Greece etc.

<sup>97</sup>However a minority of other transplant professionals think otherwise. See for instance H.Kreis, *Trans Proc*, 1987, 27, 1510-1514. Kreis quotes a study of Bart et al., *Transplantation*, 1981, 31, 379. This study discovered that potentially US kidney procurement could reach 110 p.m.p. Kreis suggests that living donation is easier for hospitals and may be relied upon instead of an attempt to maintain and increase a cadaveric programme (p1513 *ibid*).

<sup>98</sup>Kreis (*Trans Proc*, 1987, 27, 1510-1514), argues that LDT does generally act as a disincentive. He notes that in 1982 and before the number of cadaveric transplants increased slowly whilst living donation was below 5% then in 1983 when a deliberate centre policy to expand living donation was adopted for the first time since 1969 cadaveric transplants reduced.

<sup>99</sup>In other words if physicians are becoming less motivated to maintain and expand cadaveric when living donation increases, the problem is not an intrinsic one but lies in the motivational attitudes toward transplanting people within a short time. Sometimes a demotivating factor can be the fact that the financial rewards in countries with private dialysis facilities are great. On this and broader questions of motivation see a comparison and analysis of Norwegian and French practices (with particular regard to LDT), Hilde Lorentzen and Florence Paterson, *The Use of Living Donors For Kidney Transplants: Second Order and Third Order Decision Making*, copy available from OSC, FNSP CNRS, 49 Rue de L'Universite 75007 Paris.

### **3.4.3.2. Impact of LDT on the Trade in Human Organs.**

Kreis points out that commercial trading in living donor organs is inescapable in countries promoting living donation.<sup>100</sup> He concludes from this that the need for organs should be met from cadaveric donors.<sup>101</sup> However prevention of commerce is not an absolute goal;<sup>102</sup> there have been cases of trafficking in cadaveric donation and this has not been taken as a reason to stop transplantation altogether. Decisions need to be taken through a balancing of ethical and other imperatives. In practice this would probably mean regulatory control of classes of donation (e.g. non-closely genetic) more likely to be subject to 'commercial abuses' as well prohibition on conducting organ transplant activities for profit. This area is investigated further in chapter 8.

### **3.4.4. Conclusions.**

The decision of how far to use LDT to address the organ shortfall is largely a matter of weighing detriment and benefit for the donor and recipient. Subject to being able to develop an approach that mostly ensures informed and voluntary consent, the three meta conclusions that can be drawn in this area are:

- *Firstly*, given reasonably low risks to the donor, evaluating the ethics of a particular LDT involves comparing the prospective benefits to the recipient with prospective risks to both the recipient and donor. The decision to use LDT is largely based on a sufficiently favourable comparison combined with its use representing the *optimum remedium* for treatment.
- *Secondly*, psychological benefit cannot justify a procedure in itself but where LDT is the right choice for the recipient's position it may be taken into account as a factor to be balanced against detriment to the donor and used as an ethical justification,

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<sup>100</sup>*Trans Proc*, 1987, 27, 1510-1514 at 1513.

<sup>101</sup>*Ibid* at 1513.

<sup>102</sup>It is assumed for the purposes of this discussion that commerce needs preventing - for an analysis of ethical issues in this area see chapter 8.3.



alongside autonomy, for donations that have, prospectively, limited detriment. Nevertheless because *primum non nocere* is intrinsically breached by LDT to some degree<sup>103</sup> it would remain a professional right for a centre or clinician to refuse to undertake LDT in general or in particular circumstances on ethical grounds.<sup>104</sup>

- *Thirdly*, an assessment in individual cases is mainly determined by variables of pre-existing health condition of the donor and recipient, the type of procedure being undertaken and the quality of the organ being donated (including the level of match).

The majority of kidney LDT's have low risks / consequences and high anticipated benefits and can thus be justified as a better alternative than dialysis where acceptable methods of cadaveric procurement cannot fully meet demand. Liver LDT is used only where no suitable cadaver donors are available for the recipient.<sup>105</sup> Some evidence suggests that liver LDT graft survival is not as good as with its cadaveric counterpart.<sup>106</sup> Arguably this means liver LDT should continue to be used very selectively, for instance only where there is strong or chronic need, as is often the case with paediatric potential recipients. This selectivity might be broadened by the fact that the consequences of not receiving a liver transplant can ultimately be death for a liver patient whereas a kidney patient will usually simply have to endure continued dialysis.

Living lung donation has a much lower success rate<sup>107</sup> than kidney donation as well as greater risks which makes it a much more difficult procedure to justify generally but again it could be utilised in cases of strong need. Living pancreas donation is almost impossible to justify in general because of higher risks than kidney donation, combined with a significant technical failure rate and the fact that no shortage of cadaver organs are

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<sup>103</sup>F.D.Moore, 'Three Ethical Revolutions: Ancient Assumptions Remodelled Under Pressure of Transplantation' *Trans Proc*, 1988, 20(1) supp 1, 1061-1067.

<sup>104</sup>Much as a clinician can refuse to undertake an abortion.

<sup>105</sup>M.Haberal et al., 'Living Related Liver Transplantation in an Adult and A Child.' In *Organ Replacement Therapy: Ethics, Justice, Commerce* ed W.Land and J.Dossetor, *Springer Verlag*, 1991, 83-91.

<sup>106</sup>R.W.Busutill, 'Living Related Liver Donation: CON,' *Trans Proc*, 1991, 23, 43-45.

<sup>107</sup>L.R.Shaw et al., *The Lancet*, 1991, 338, 678-681. Graft survival rates are quoted at 65% for one year and 53% at 3 years.

available. Probably the only situation in which it could seriously be considered is where cadaveric donation cannot easily be used, for instance with highly sensitised diabetics.

### **3.5. Conclusions.**

The extent to which reliance is placed on LDT varies widely between countries. Some differences are due to geography<sup>108</sup> or differing supply needs.<sup>109</sup> However, differing usage is seemingly also significantly due to differing understandings and perspectives on LDT ethics, particularly amongst practitioners (see chapter 10). At the one extreme a number of surgeons prefer LDT organs to cadaveric organs<sup>110</sup> and, at the other extreme, a significant proportion of clinicians regard LDT as unethical.<sup>111</sup> Attitudes of clinicians are a key to determining practice and even the regulatory framework for LDT. Currently criteria for living donor usage varies widely between countries, regions, centres and different clinicians and are often not clearly established at all. Indeed the overall picture is "ad hoc and unsystematic."<sup>112</sup> It is essential that the direction of procurement policy is not superimposed on centres and countries but, equally, extensive LDT use must be placed firmly on the agenda and subjected to a clear analysis of the ethical and legal pre-conditions for usage and the respective rights and responsibilities of participants and practitioners.

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<sup>108</sup>In Norway geographical / transportation issues make dialysis more difficult.

<sup>109</sup>As is the case with Eire where by the use of cadaver alone the waiting list is kept to a small level.

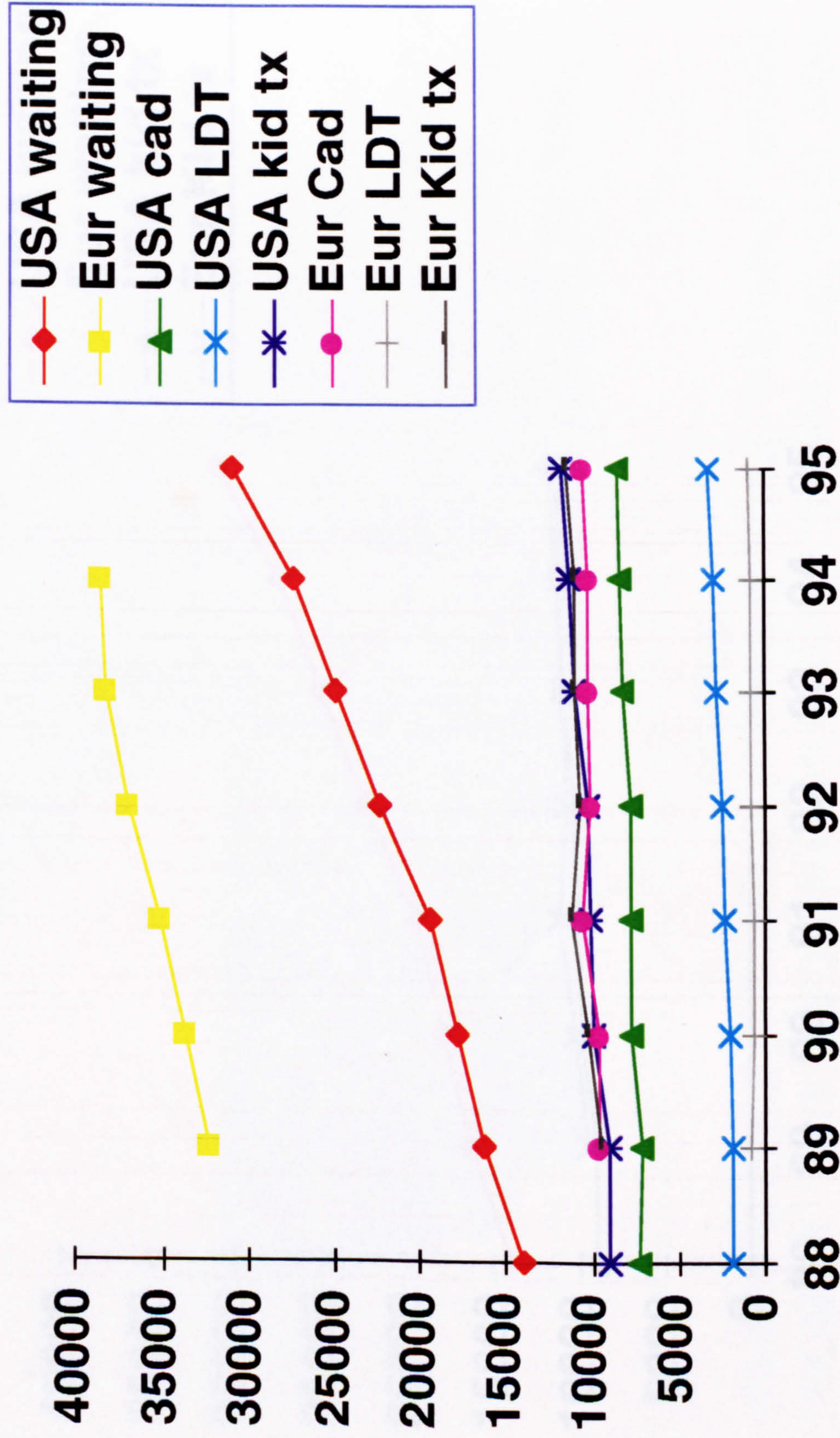
<sup>110</sup>A.Spital et al. in their study of US transplant centres found 36% of surgeons with this view (*Transplantation* 1993, 48 at 243-248).

<sup>111</sup>Editorial, *Lancet*, 1982, ii, 696. In this study of 148 European Transplant Centres 22% of surveyed doctors thought LDT was ethically unacceptable.

<sup>112</sup>B.New et al., Kings Fund Research Report 18, 83.

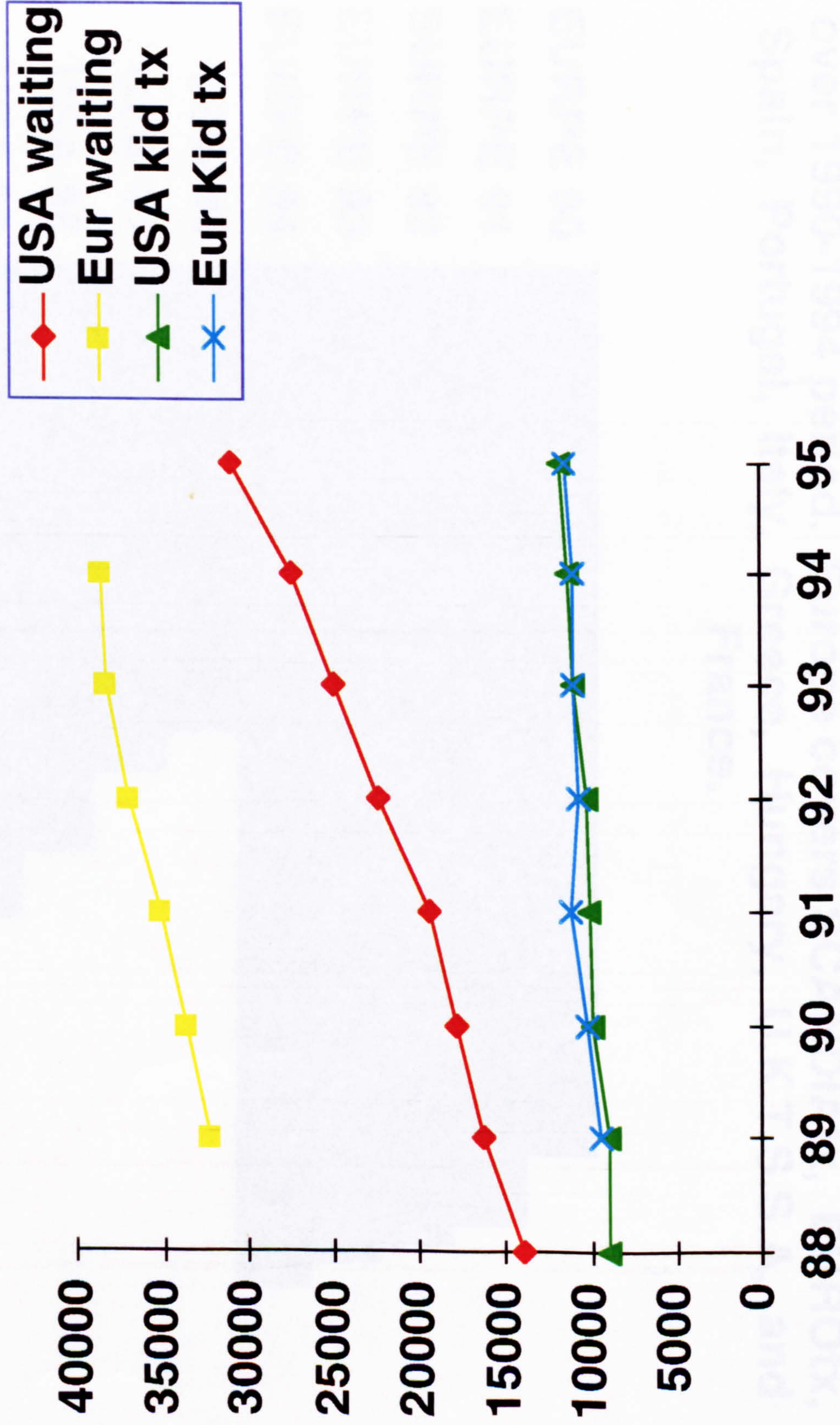


**Graph 1: Kidney Transplant Waiting Lists vis a vis Numbers of Kidney Transplants Performed Annually in Europe (Scandia, EUROtx, Hungary, U.K.T.S.S.A., Portugal, Spain, Italy, Greece, Switzerland) and U.S.A.**



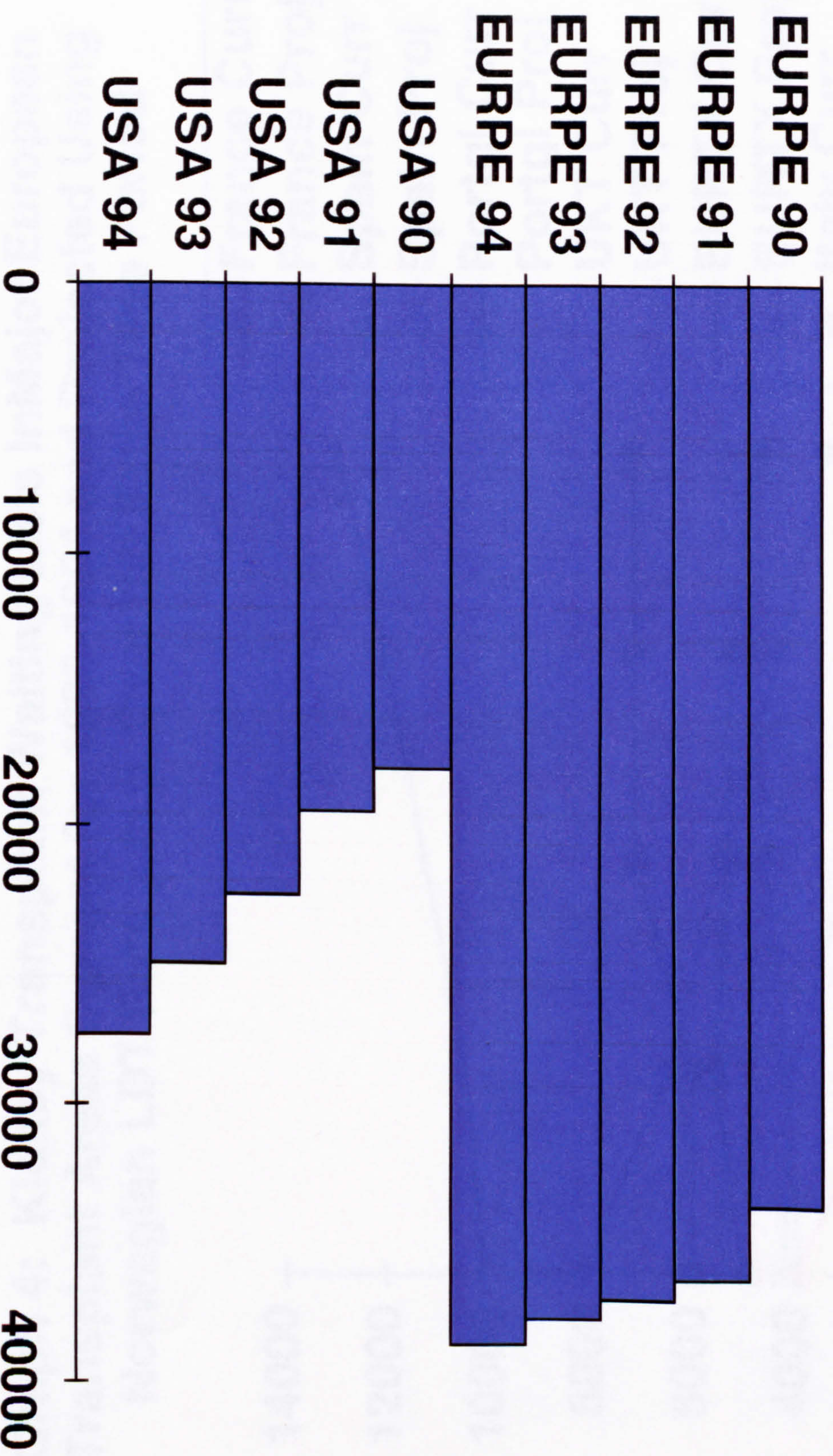


**Graph 2: Kidney Transplant Waiting Lists vis a vis Numbers of Kidney Transplants Performed Annually in Europe (Scandia, EUROtx, Hungary, U.K.T.S.S.A., Portugal, Spain, Italy, Greece, Switzerland) and U.S.A.**



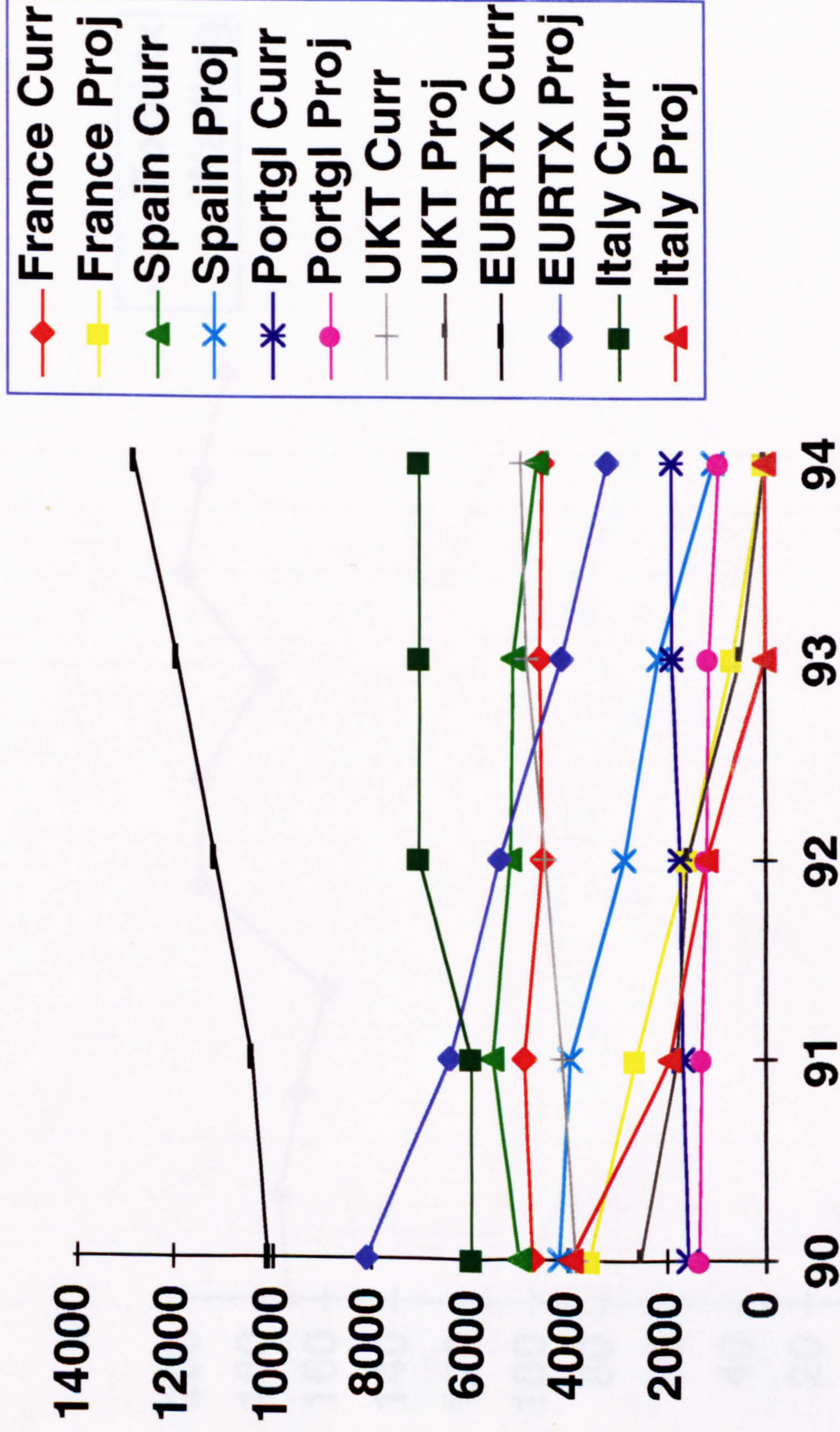


**Graph 3: Comparison of waiting lists in Europe with U.S.A. over 1990-1994 period. Europe covers SCANDIAtx, EUROtx, Spain, Portugal, Italy, Greece, Hungary, U.K.T.S.S.A, and France.**



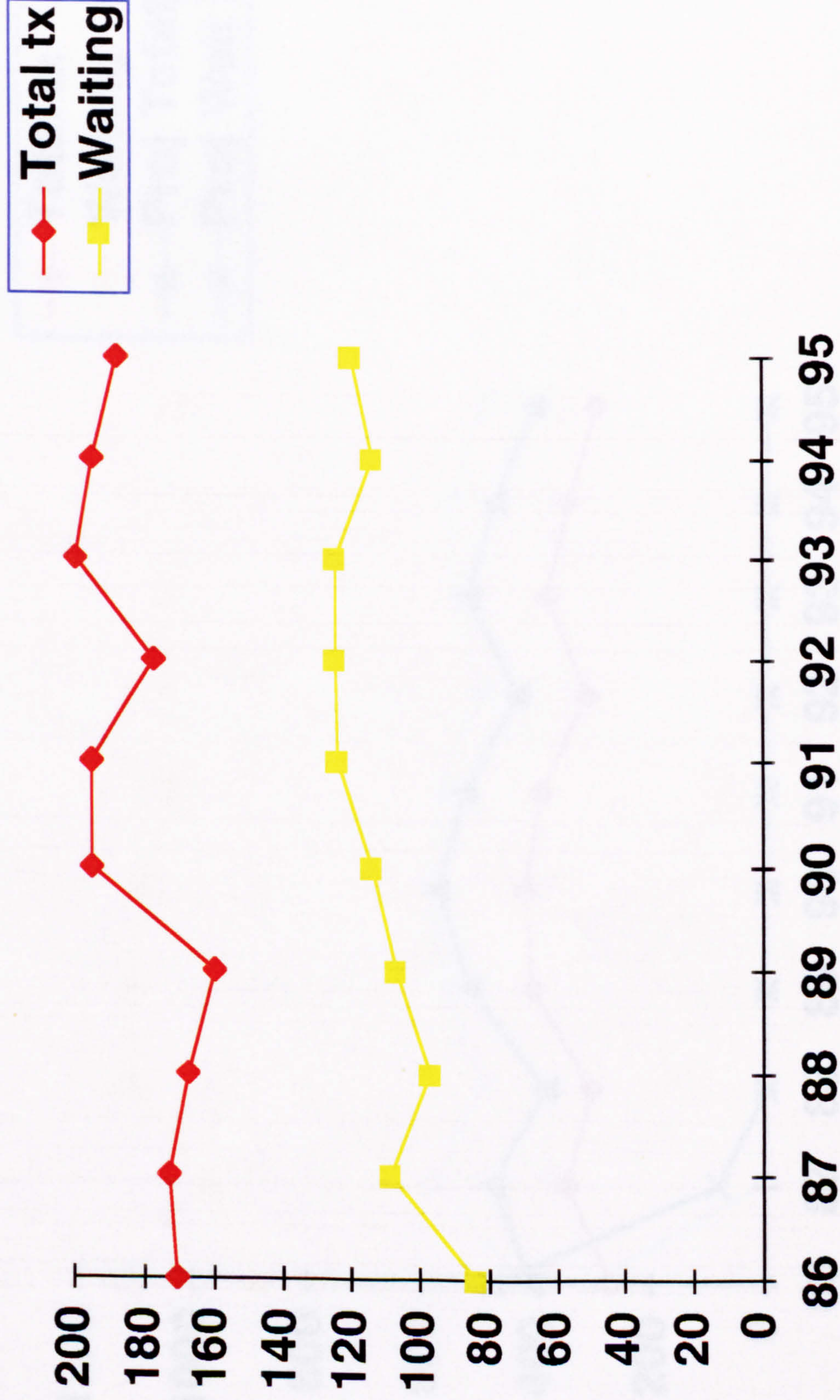


**Graph 4: Kidney Transplant Waiting Lists In Major European Transplant Areas Current for 1990-1994 and Projected Using Norwegian LDT Rate p.m.p. Over the Same Time Period**



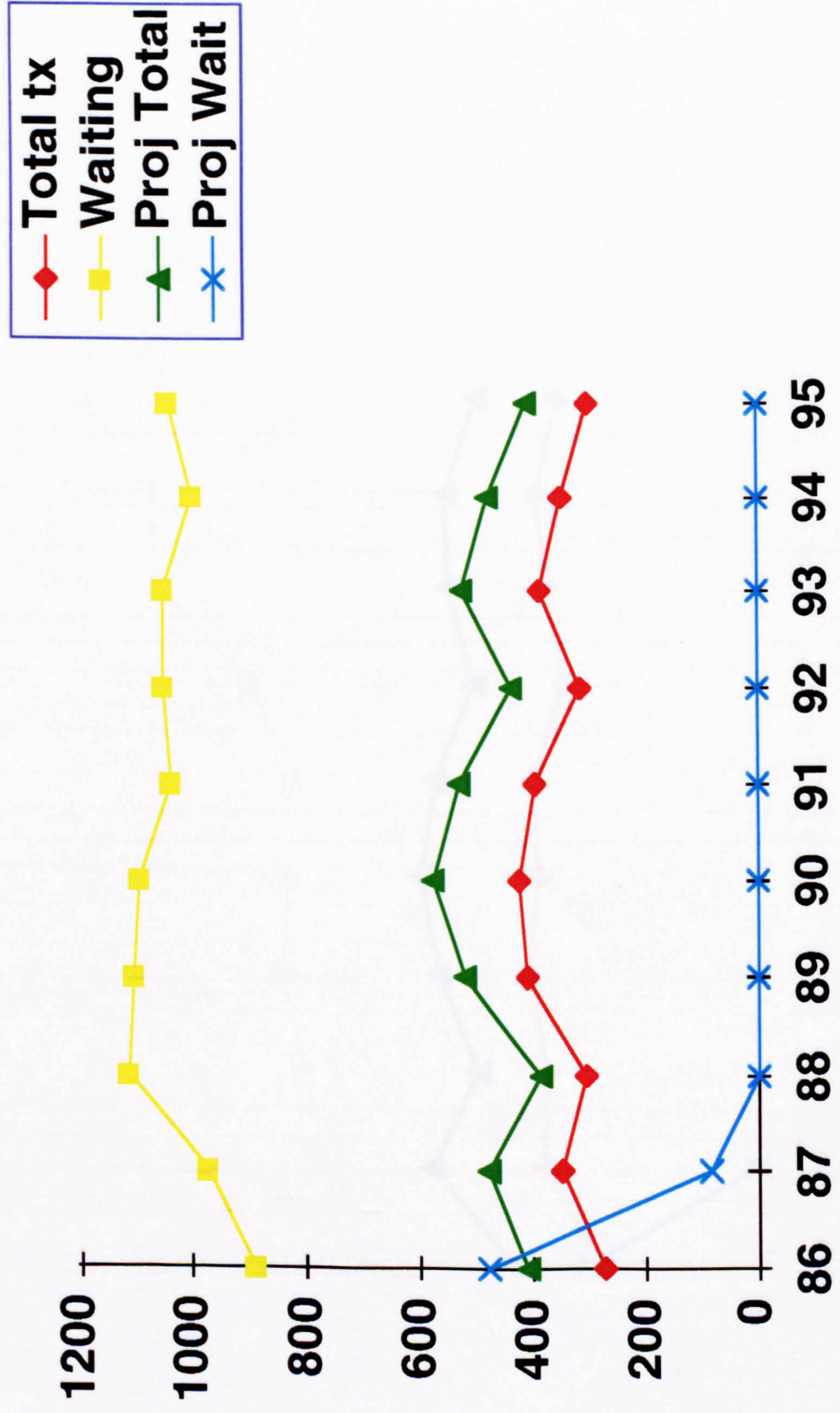


**Graph 5: Norway Kidney Transplant Waiting List / Numbers of Kidney Transplants Performed Annually.**



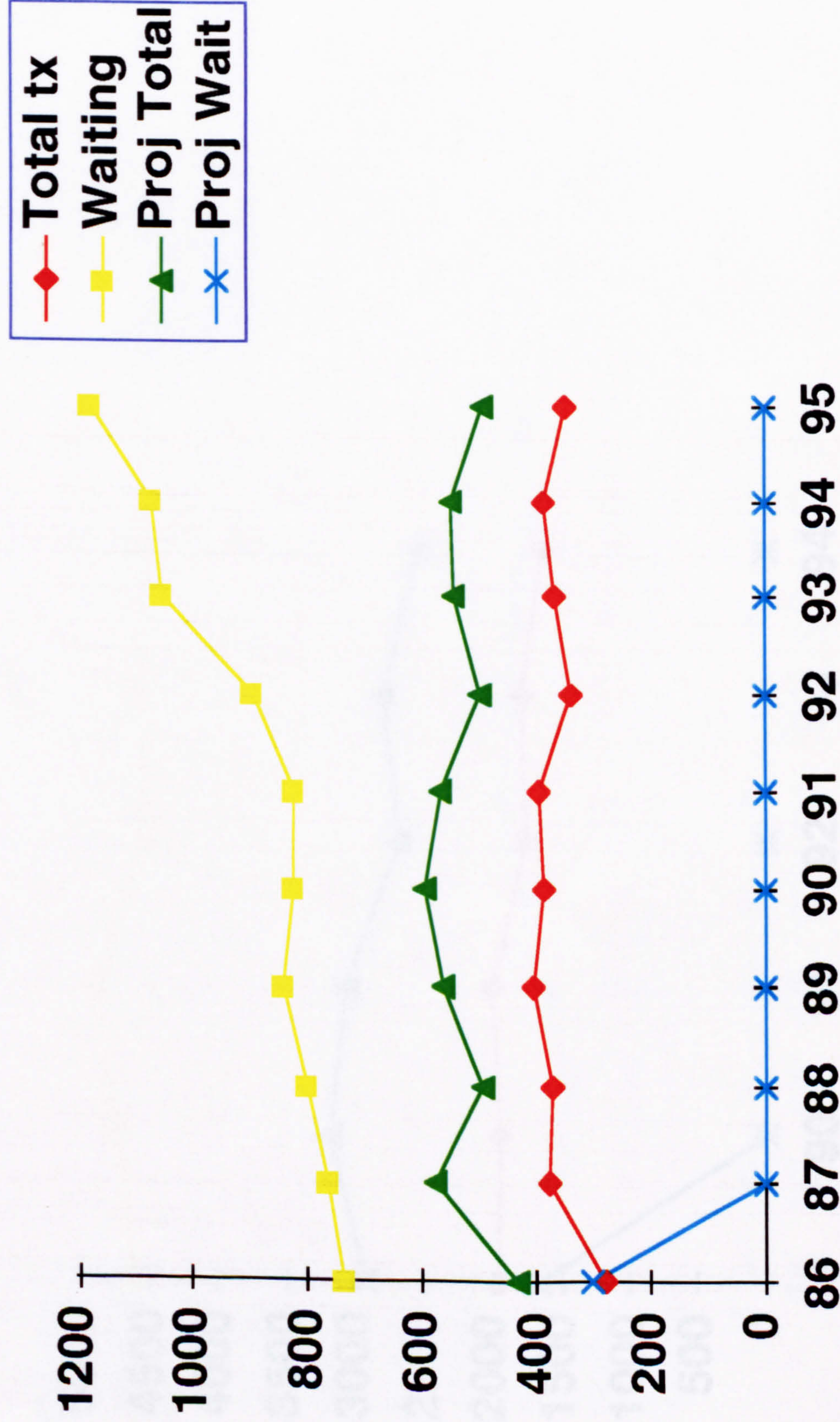


**Graph 6: Austria Kidney Transplant Waiting List / Numbers of Kidney Transplants Performed Annually and Projected Waiting List Numbers of Transplants Utilizing Norwegian Rate of LDT p.m.p. Over Corresponding Time Period.**



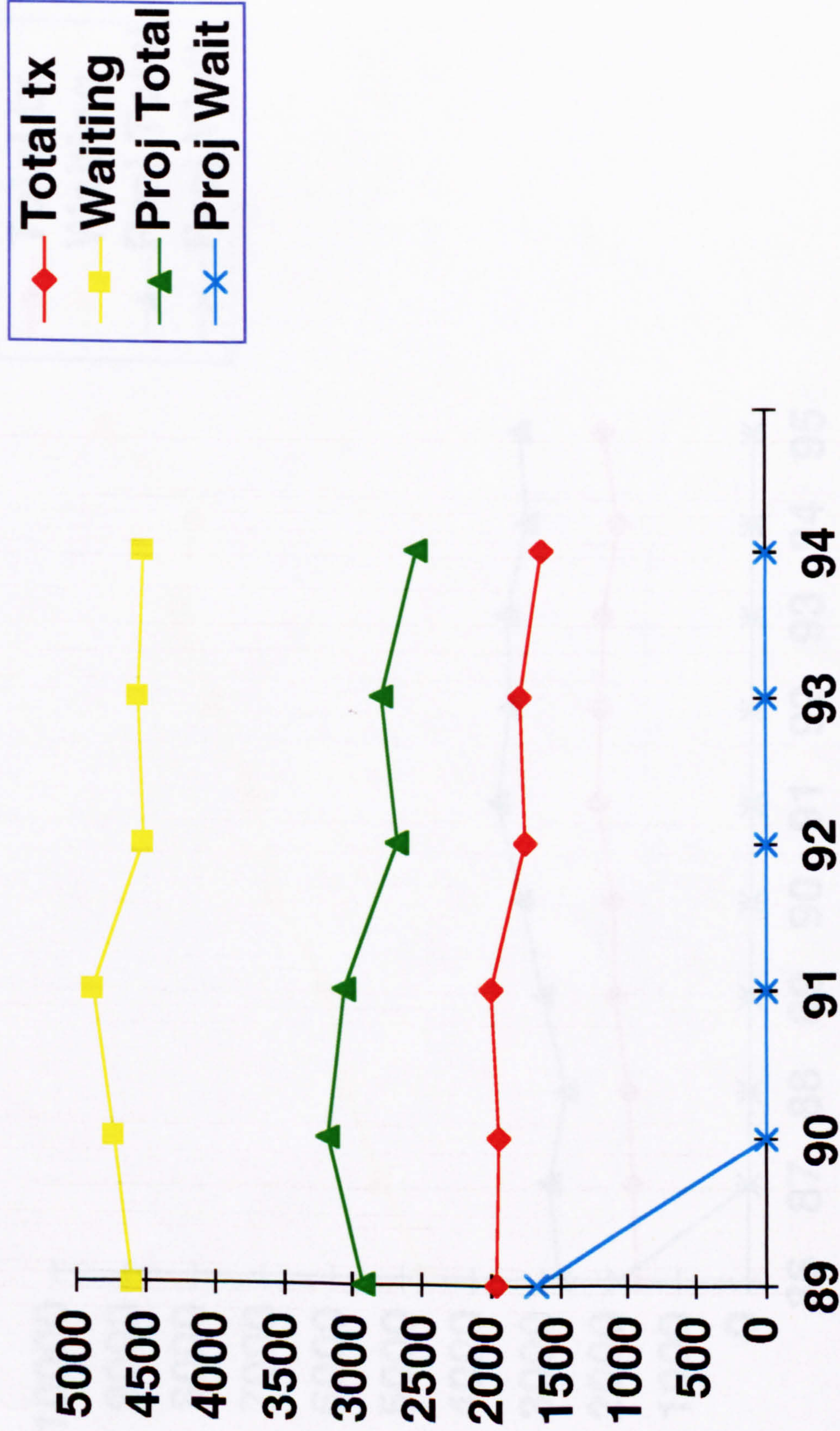


**Graph 7: Belgium Kidney Transplant Waiting List / Numbers of Kidney Transplants Performed Annually and Projected Waiting List Numbers of Transplants Utilizing Norwegian Rate of LDT p.m.p. Over Corresponding Time Period.**



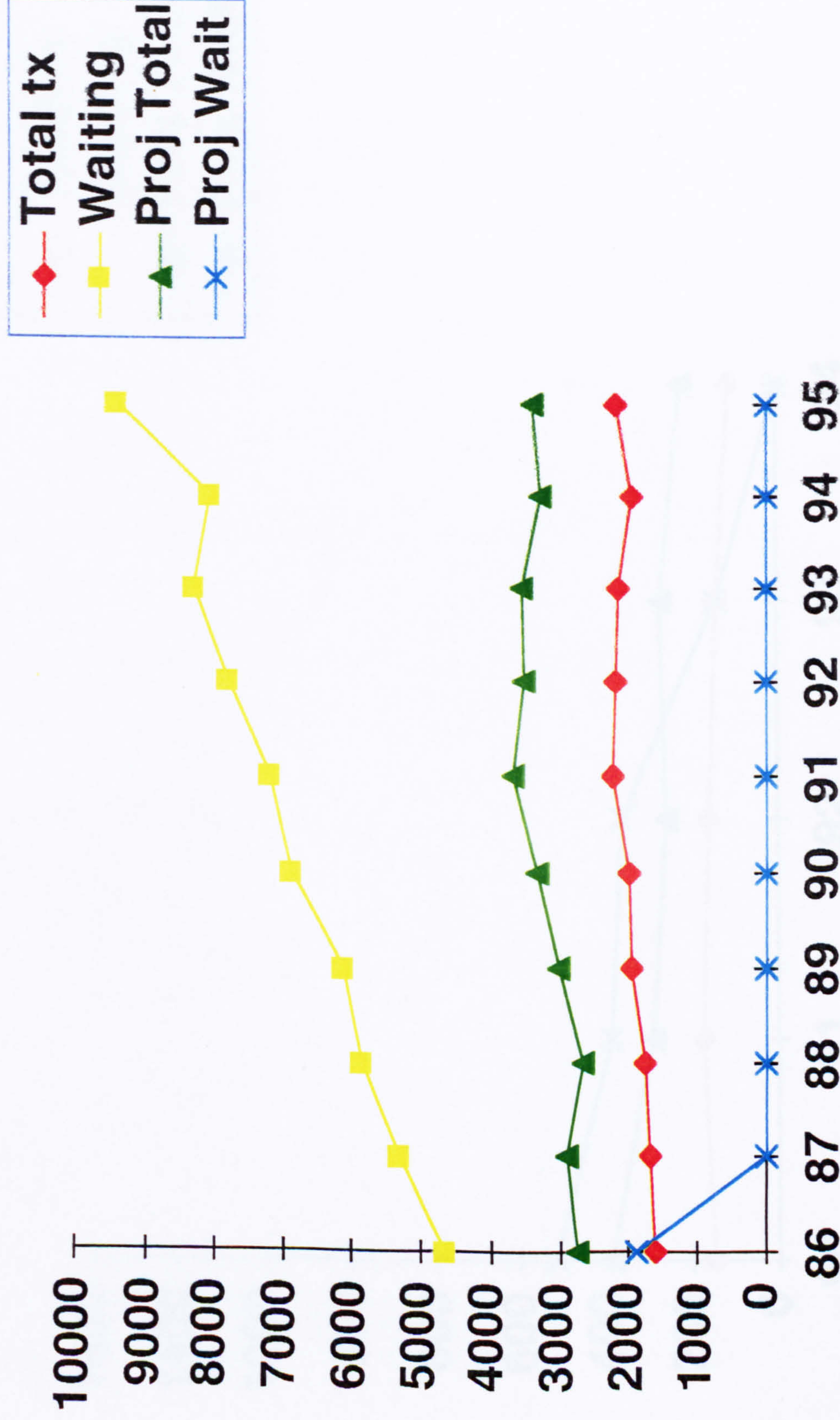


Graph 8: France Kidney Transplant Waiting List / Numbers of Kidney Transplants Performed Annually and Projected Waiting List Numbers of Transplants Utilizing Norwegian Rate of LDT p.m.p. Over Corresponding Time Period.



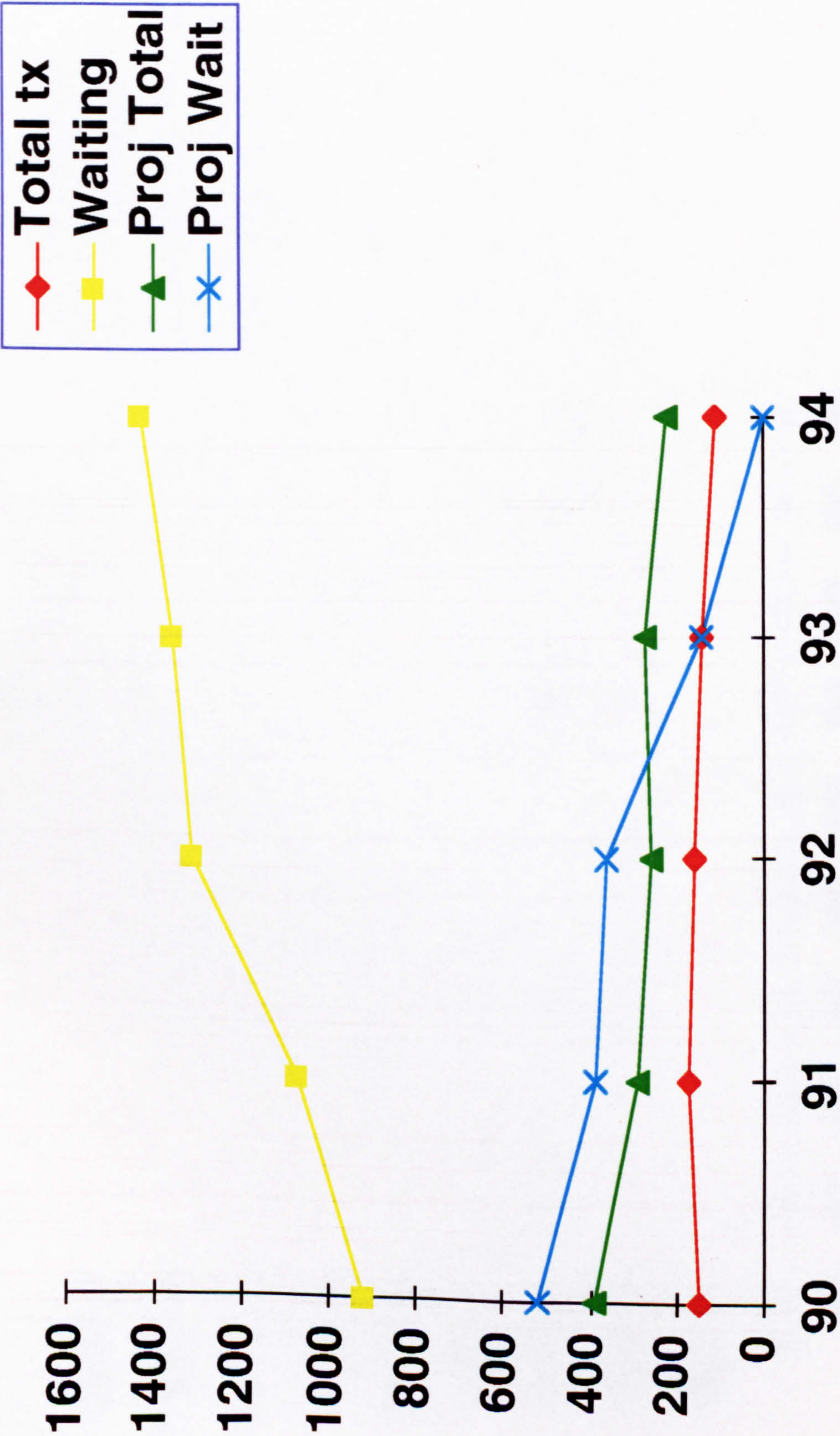


**Graph 9: Germany Kidney Transplant Waiting List / Numbers of Kidney Transplants Performed Annually and Projected Waiting List Numbers of Transplants Utilizing Norwegian Rate of LDT p.m.p. Over Corresponding Time Period.**



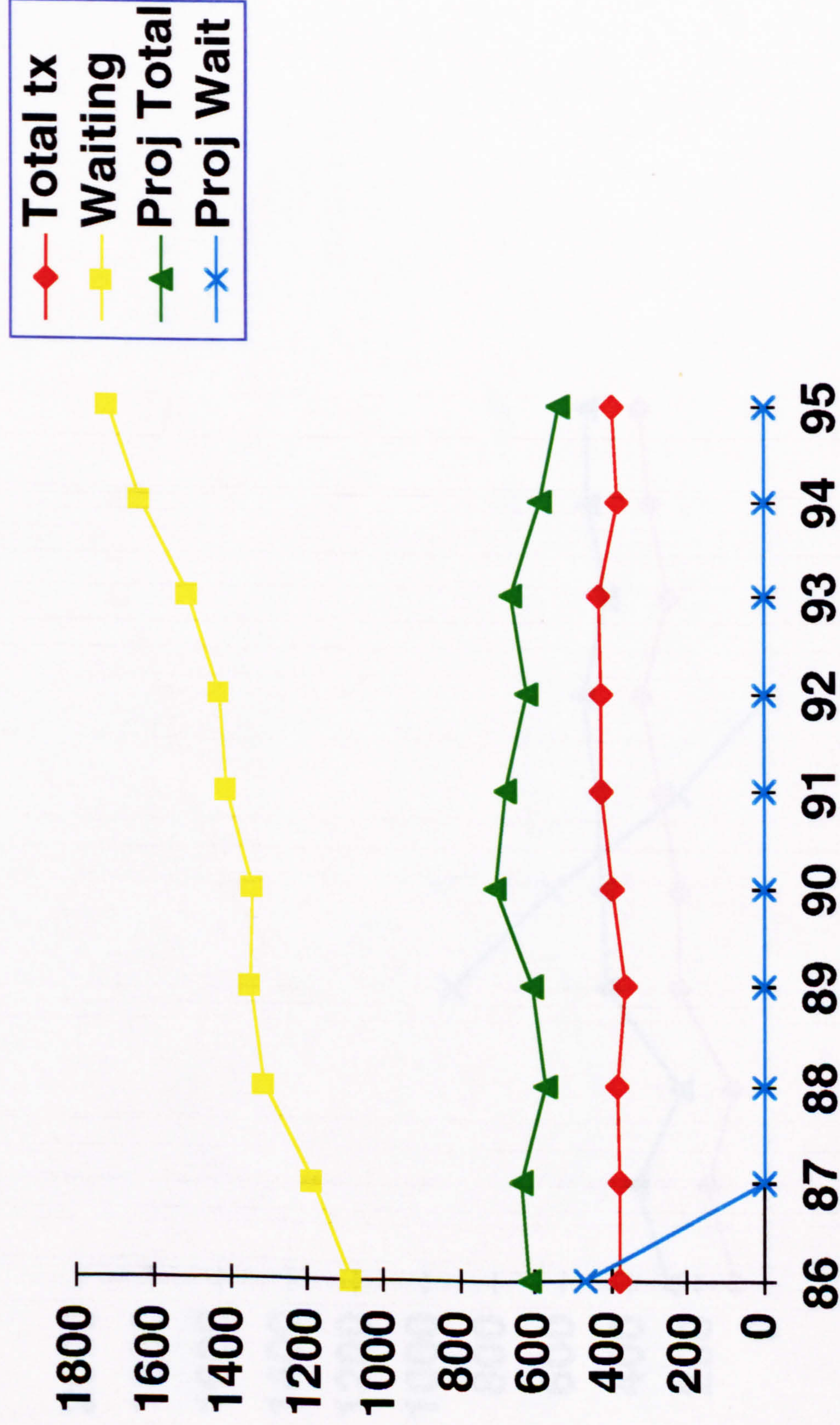


**Graph 10: Greece Kidney Transplant Waiting List / Numbers of Kidney Transplants Performed Annually and Projected Waiting List Numbers of Transplants Utilizing Norwegian Rate of LDT p.m.p. Over Corresponding Time Period.**



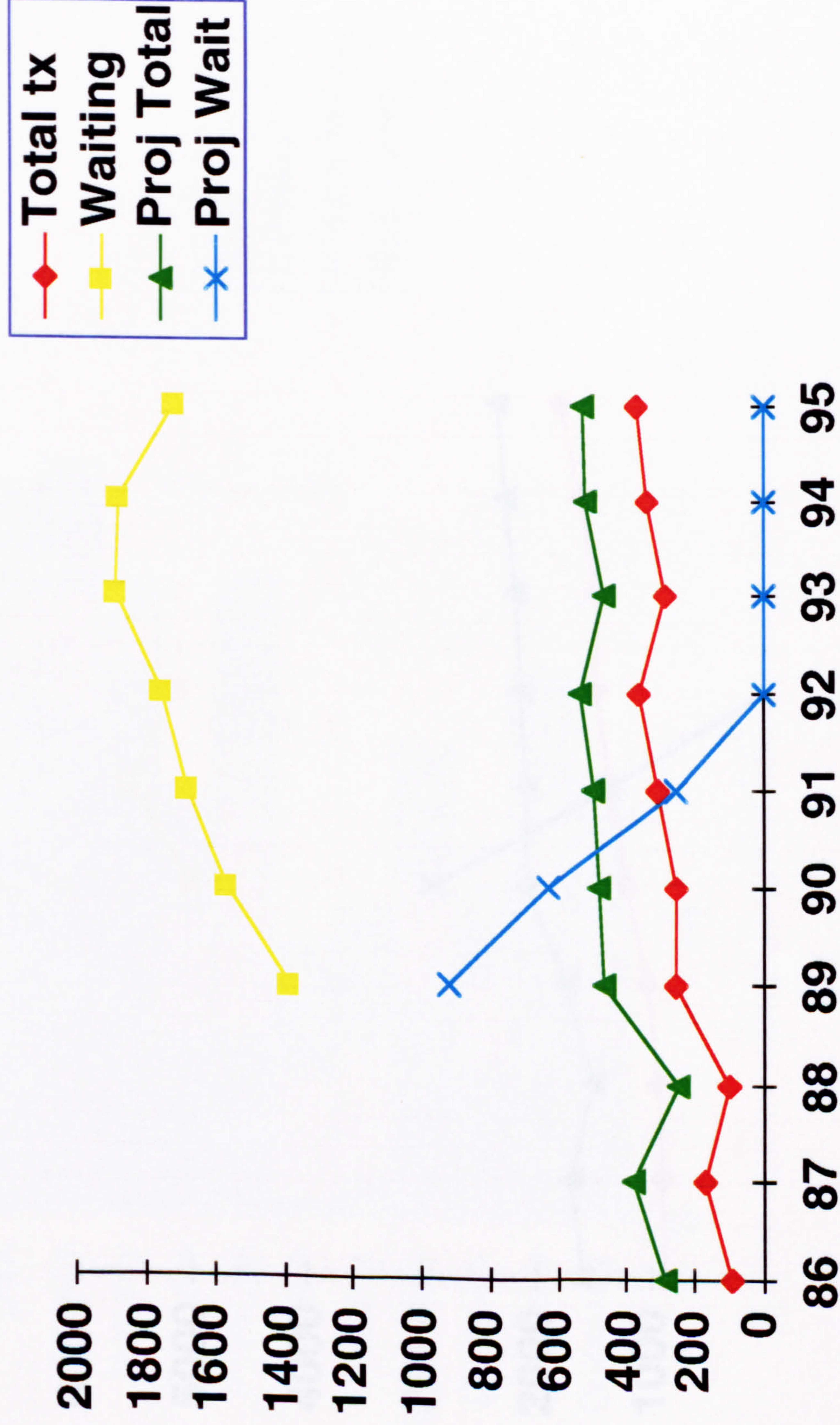


**Graph 11: Netherlands Kidney Transplant Waiting List /  
 Numbers of Kidney Transplants Performed Annually and  
 Projected Waiting List Numbers of Transplants Utilizing  
 Norwegian Rate of LDT p.m.p. Over Corresponding Time Period.**



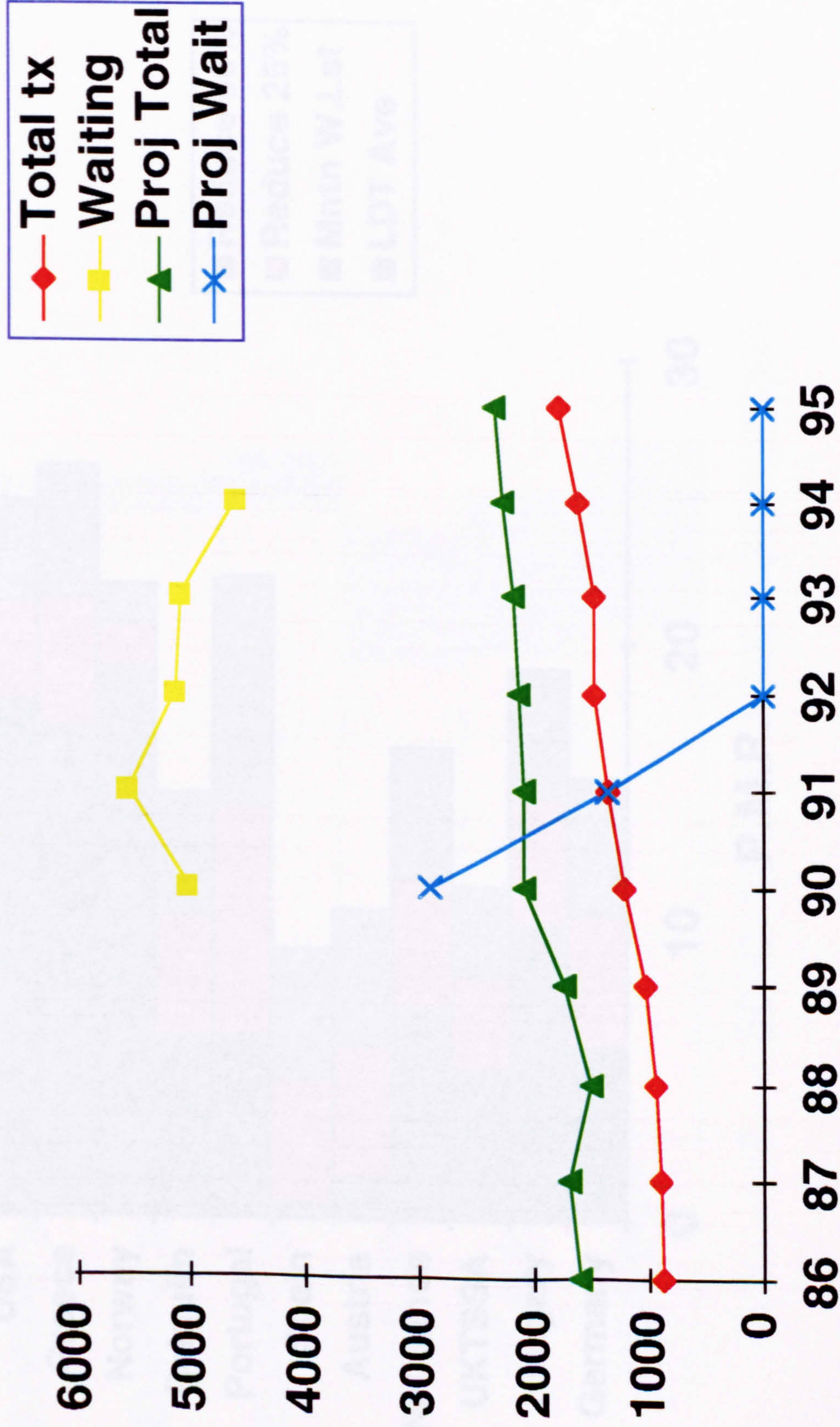


**Graph 12: Portugal Kidney Transplant Waiting List / Numbers of Kidney Transplants Performed Annually and Projected Waiting List Numbers of Transplants Utilizing Norwegian Rate of LDT p.m.p. Over Corresponding Time Period.**



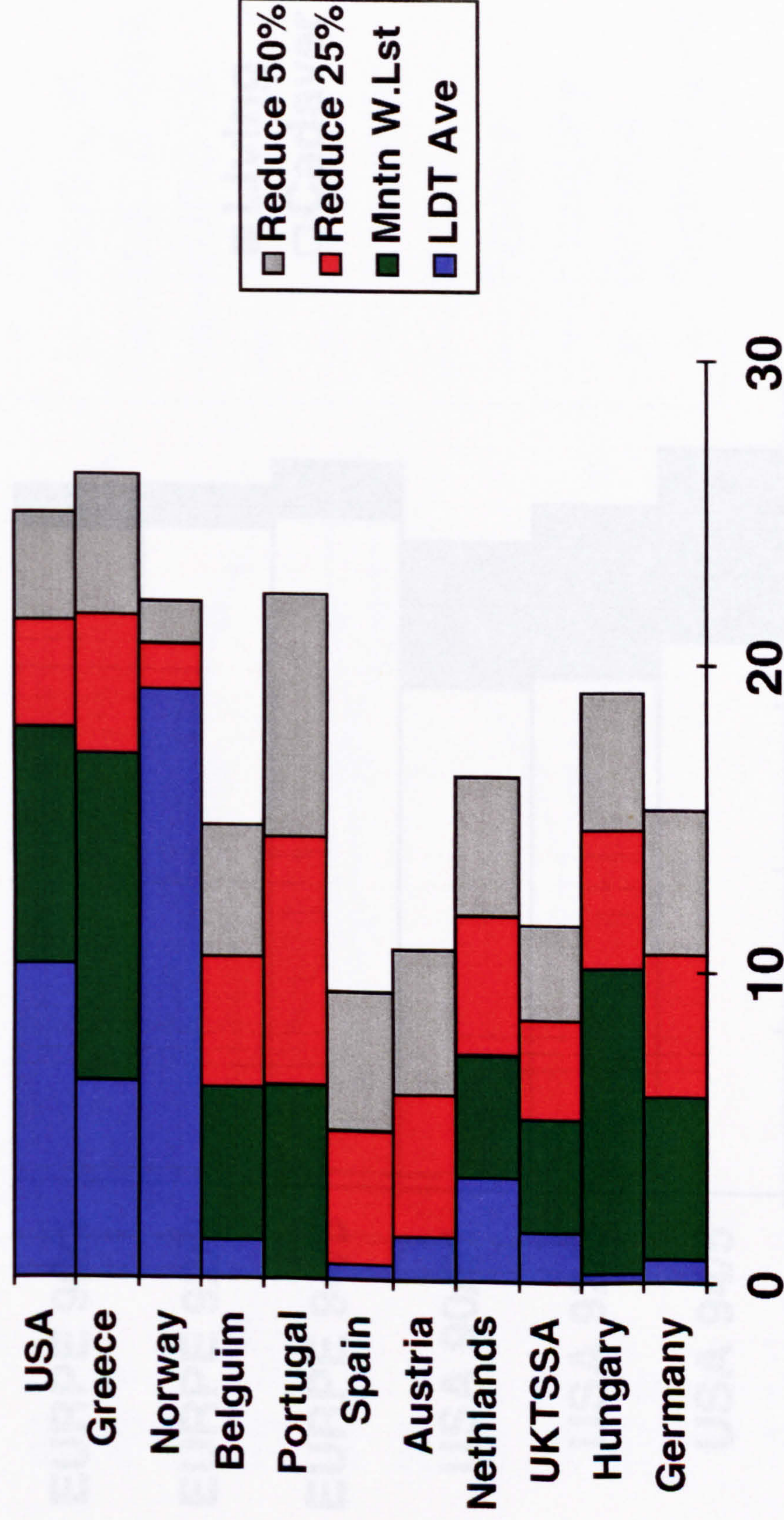


**Graph 13: Spain Kidney Transplant Waiting List / Numbers of Kidney Transplants Performed Annually and Projected Waiting List Numbers of Transplants Utilizing Norwegian Rate of LDT p.m.p. Over Corresponding Time Period.**



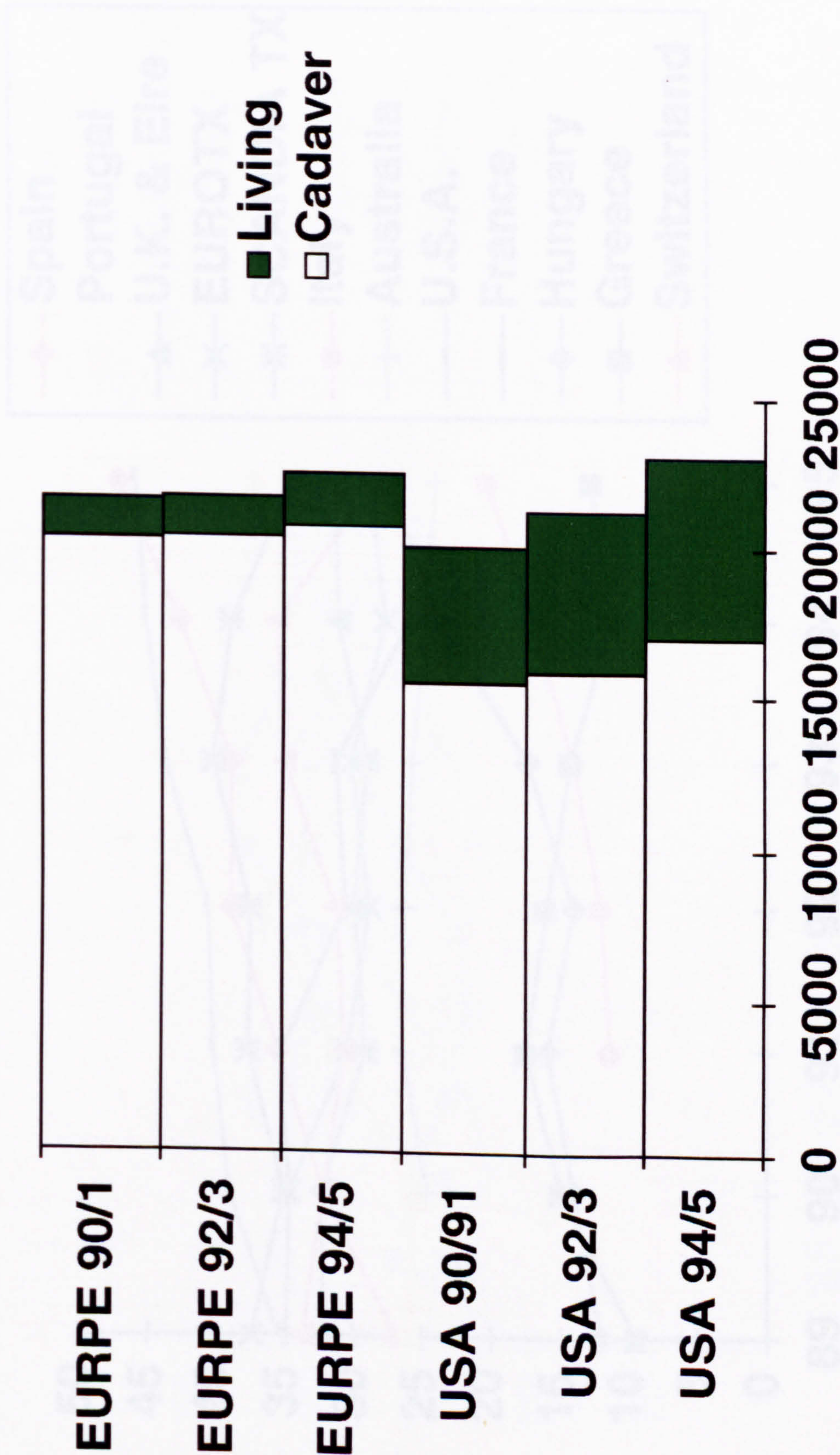


**Graph 14: Projected Impact of LDT Strategies Over a 5 Year Period: LDT p.m.p. Annual Average (1990-1994), Projected Annual Average Increases in LDT p.m.p. Required To Maintain Waiting List at 1990 Level and to Reduce 1990 Waiting Lists by 25% and 50%.**



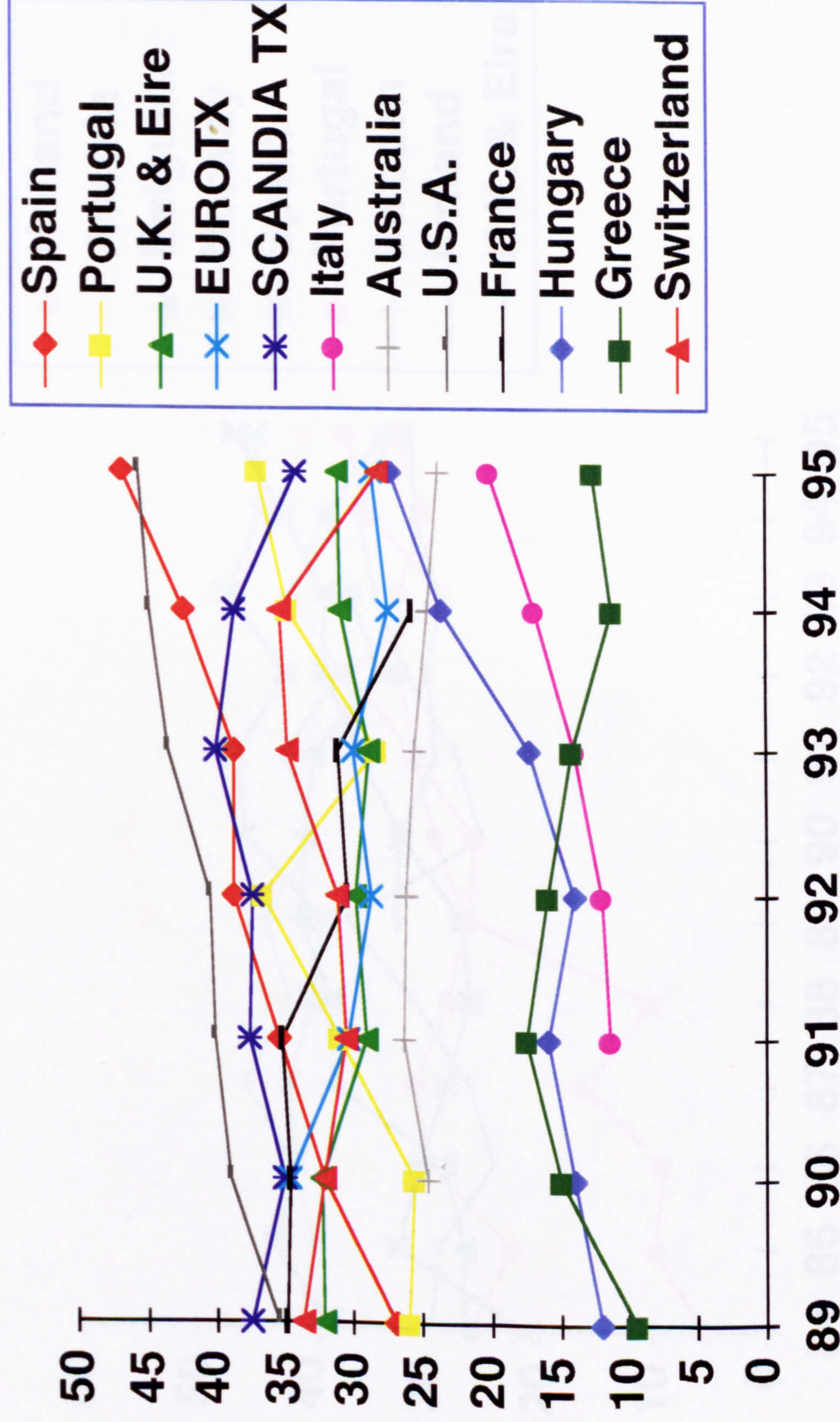


**Graph 15: Comparison of numbers of kidneys transplanted in 1990&91 with 92&93 and 94-5 in Europe (inclusive of SCANDIAtx, EUROtx, Spain, Portugal, Italy, Greece, Hungary, U.K.T.S.S.A, and France) and USA.**



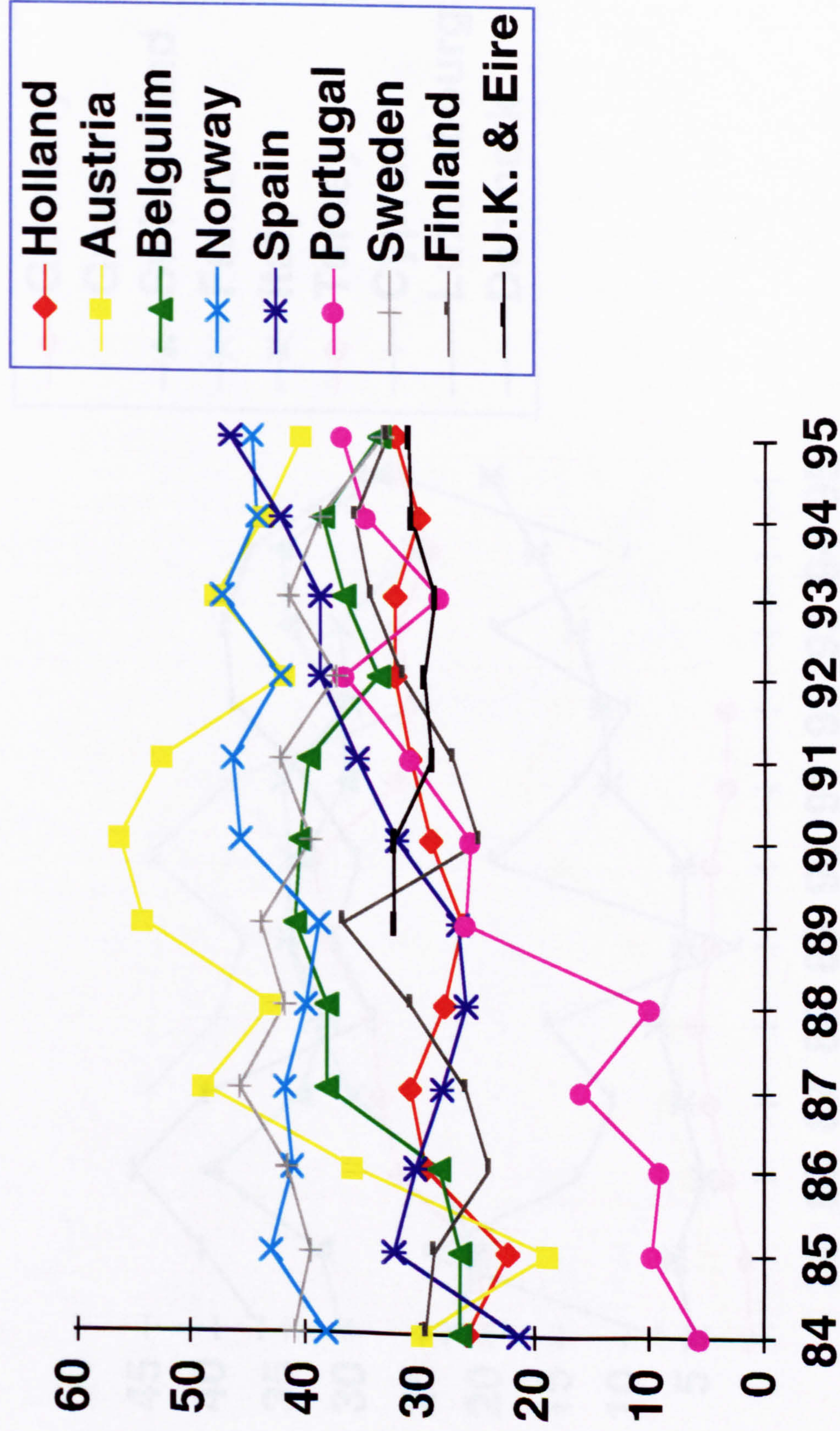


**Graph 16: KIDNEY TRANSPLANTS PMP ANNUALLY IN SOME MAJOR TRANSPLANT AREAS.**



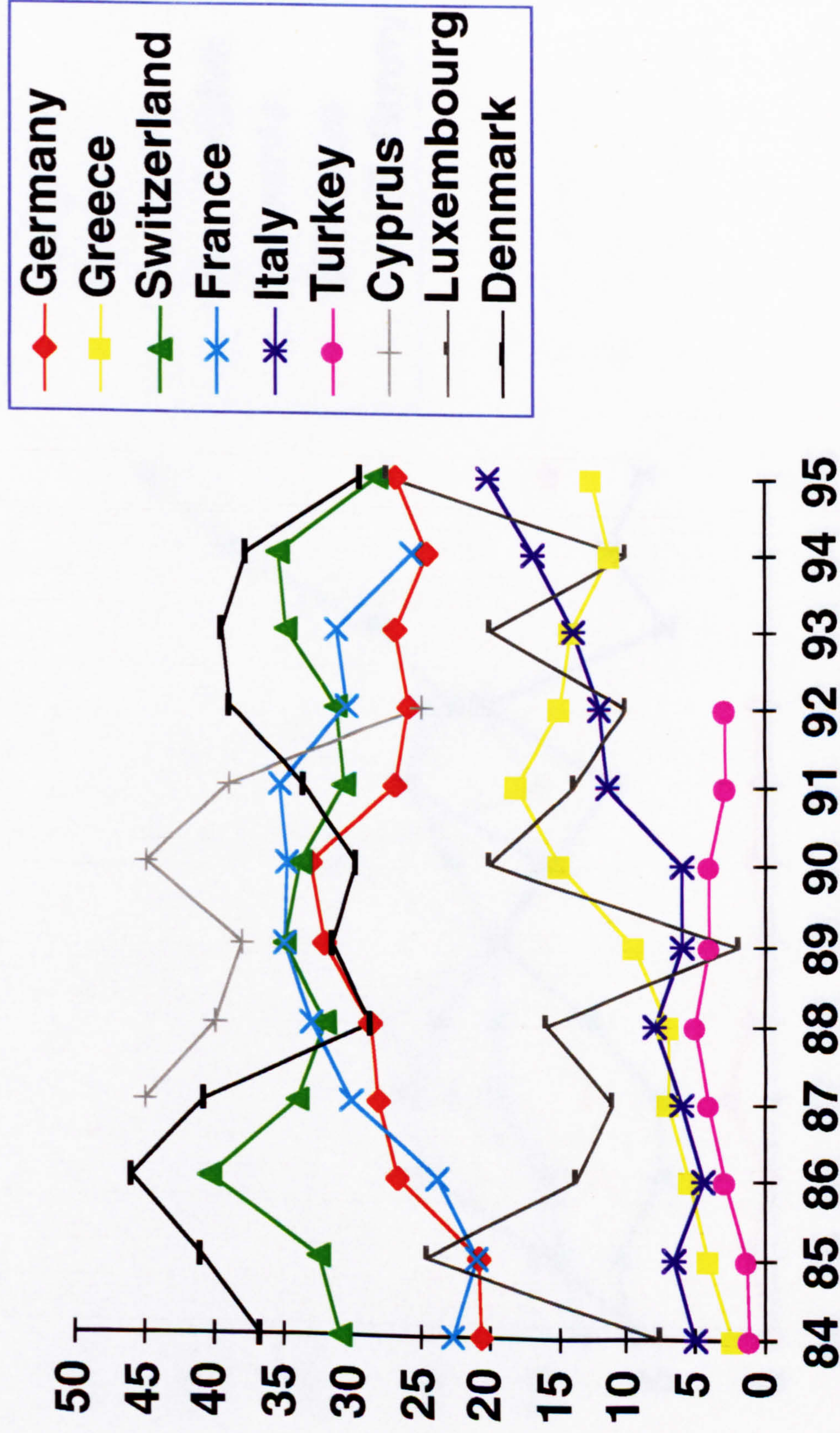


**Graph 17: KIDNEY TRANSPLANTS CURRENTLY 30+ PMP  
ANNUALLY IN WESTERN EUROPEAN COUNTRIES.**



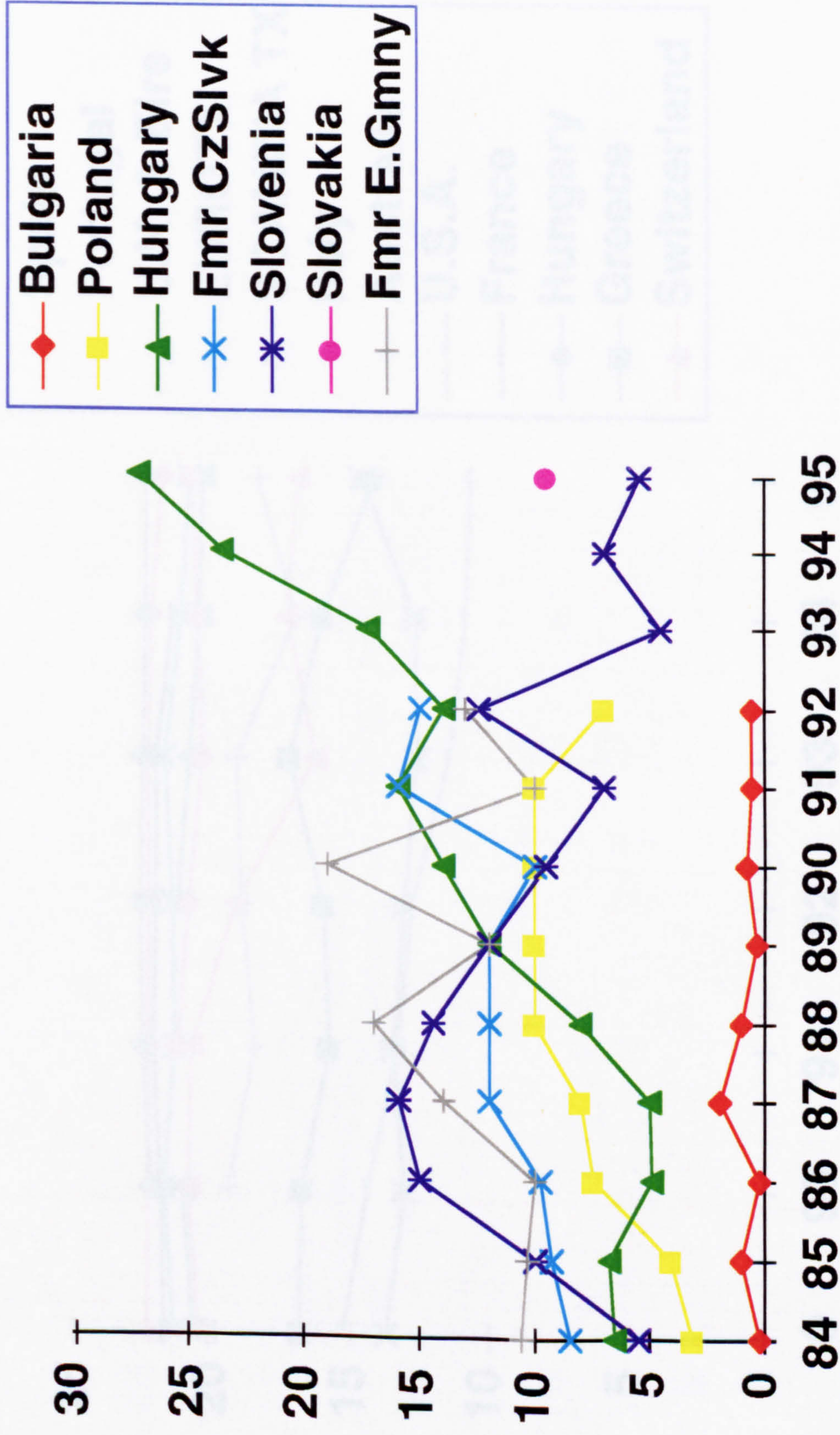


**Graph 18: KIDNEY TRANSPLANTS CURRENTLY LESS THAN 35 PMP ANNUALLY IN WESTERN EUROPEAN COUNTRIES.**





**Graph 19: NUMBERS OF TRANSPLANTS PMP ANNUALLY IN FORMER EASTERN AND CENTRAL EUROPEAN COUNTRIES.**

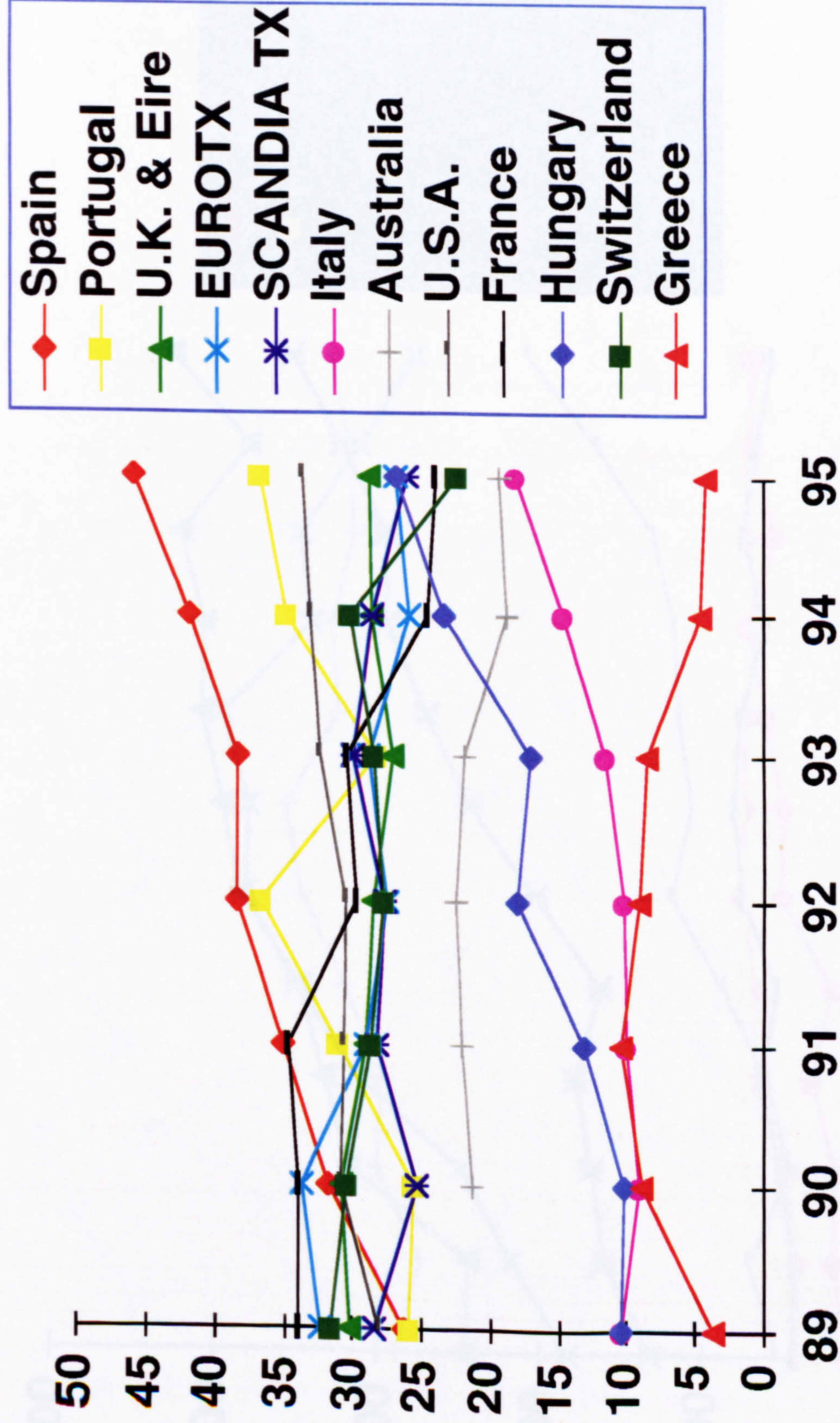






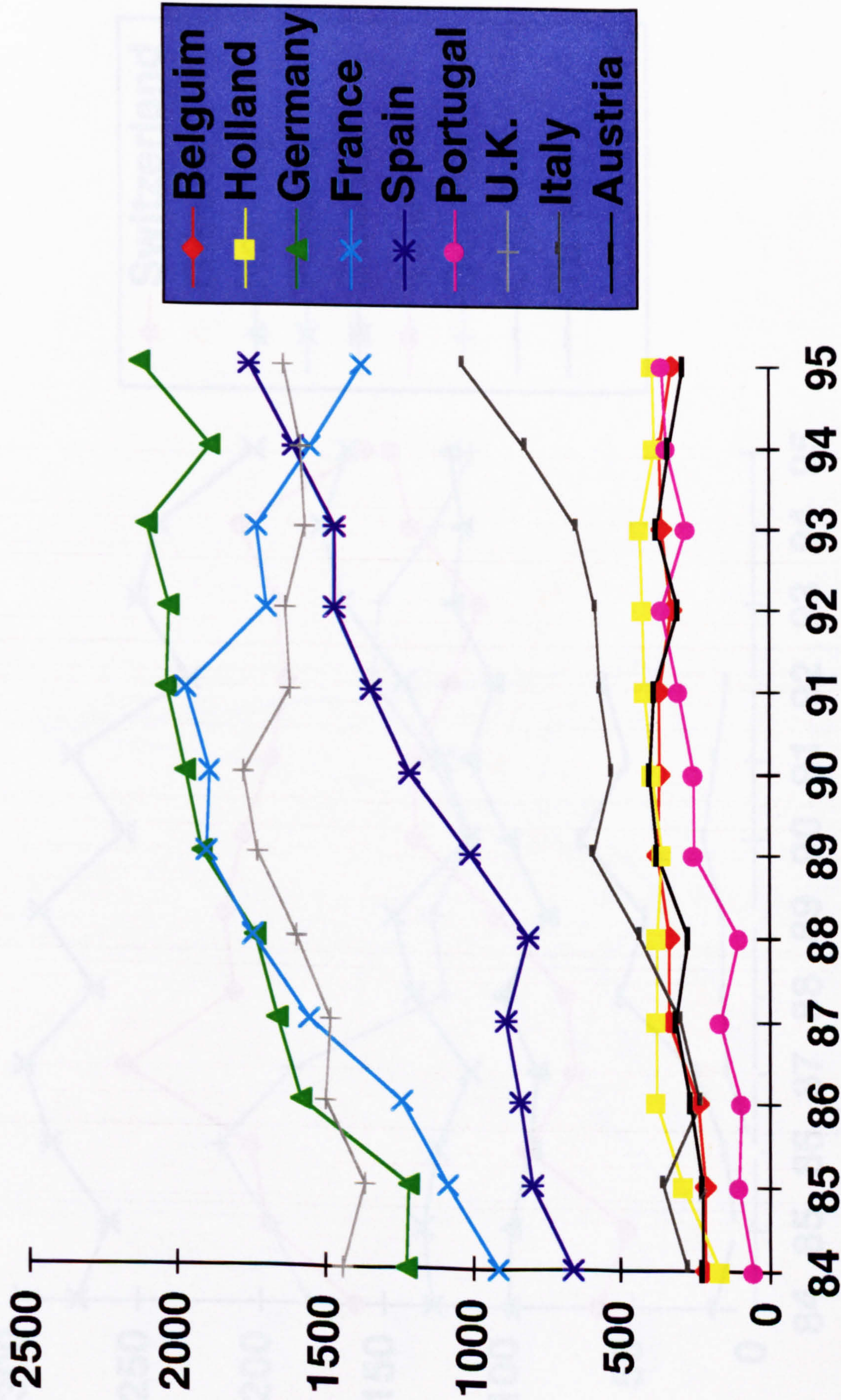


**Graph 21: CADAVERIC KIDNEY TRANSPLANTS PMP  
ANNUALLY IN SOME MAJOR TRANSPLANT AREAS.**



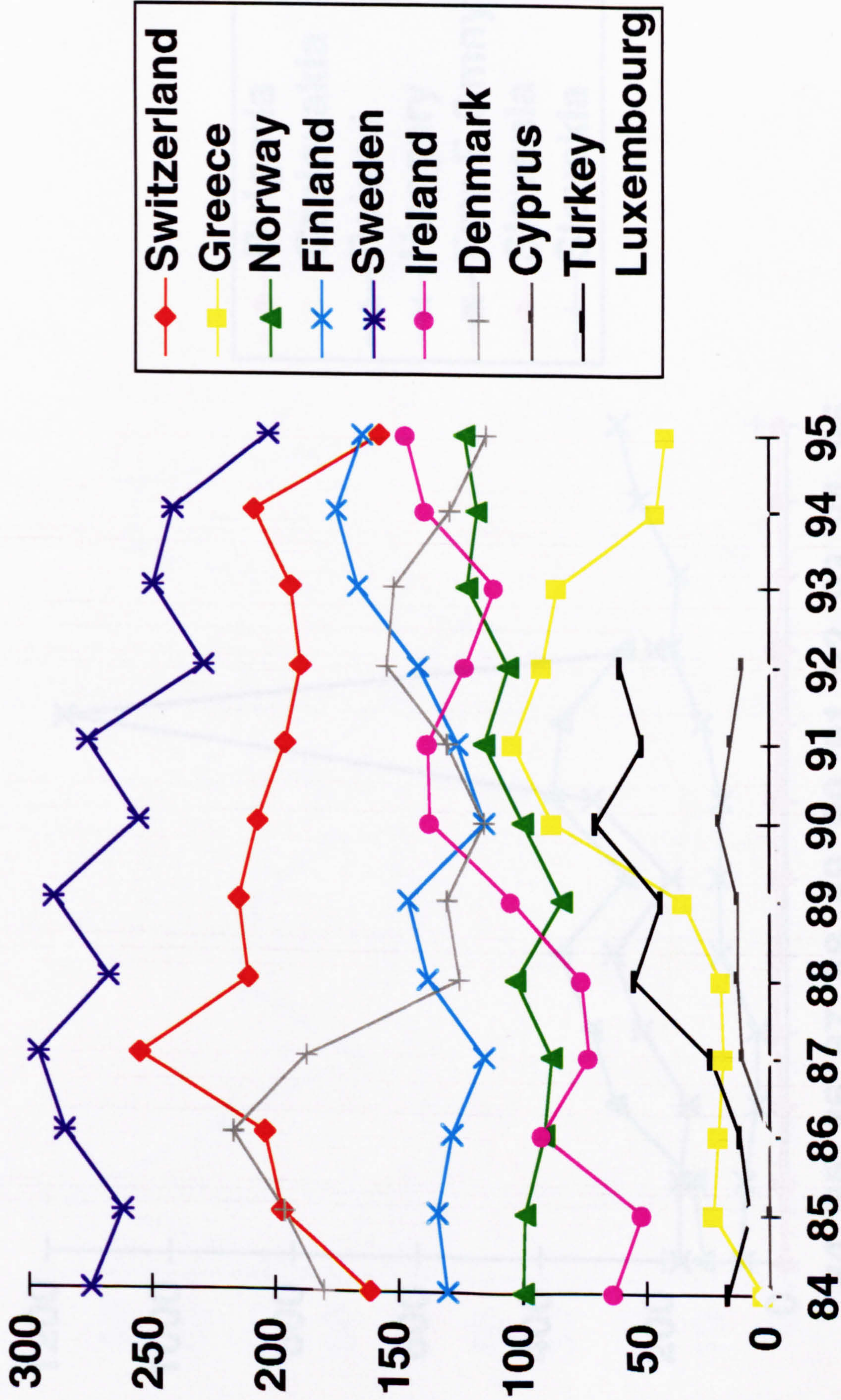


**Graph 22: ANNUAL CADAVERIC KIDNEY TRANSPLANTS IN WESTERN EUROPEAN COUNTRIES ANNUALLY WHERE 300+.**



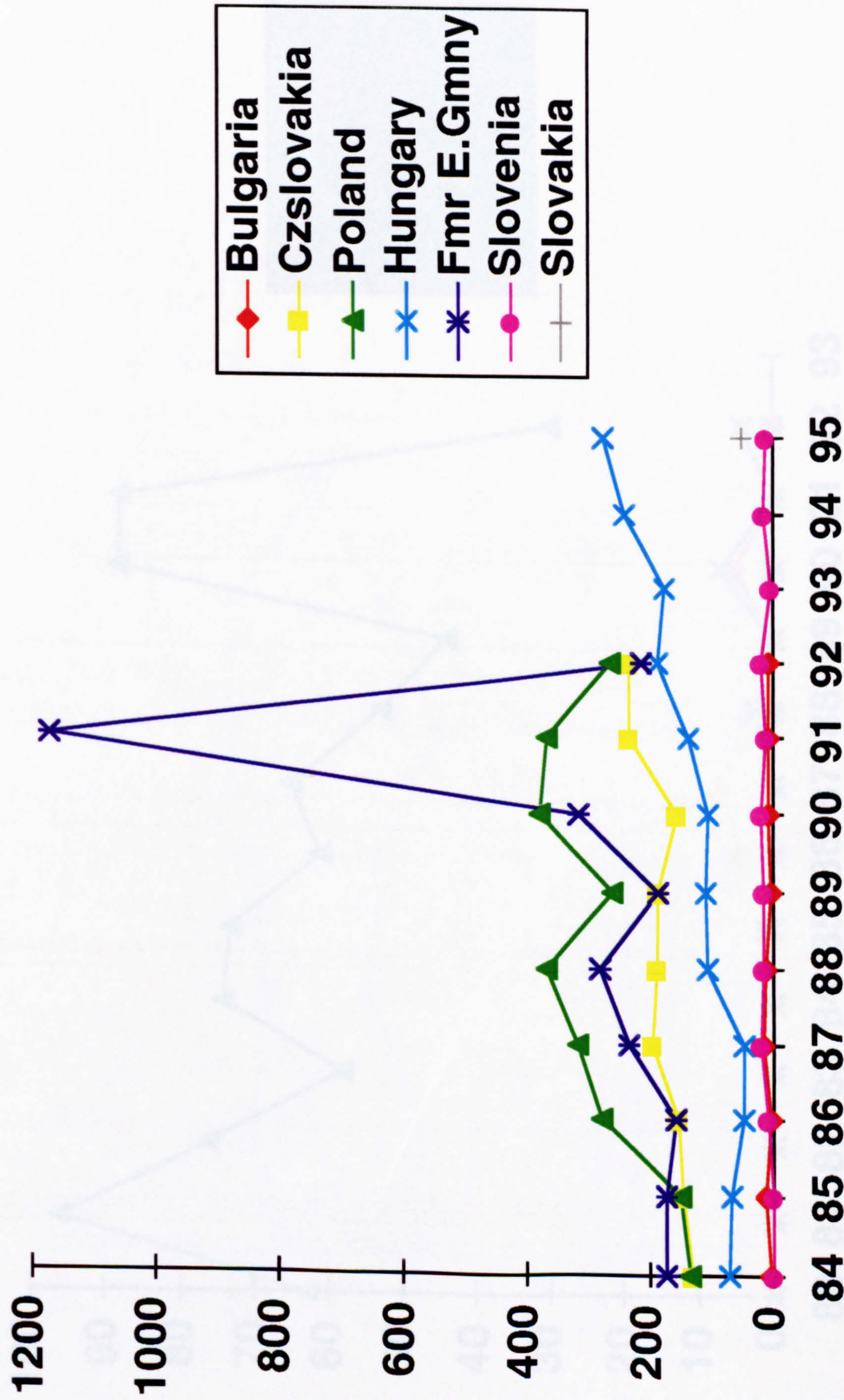


**Graph 23: CADAVERIC KIDNEY TRANSPLANTS IN WESTERN EUROPEAN COUNTRIES ANNUALLY WHERE LESS THAN 300.**



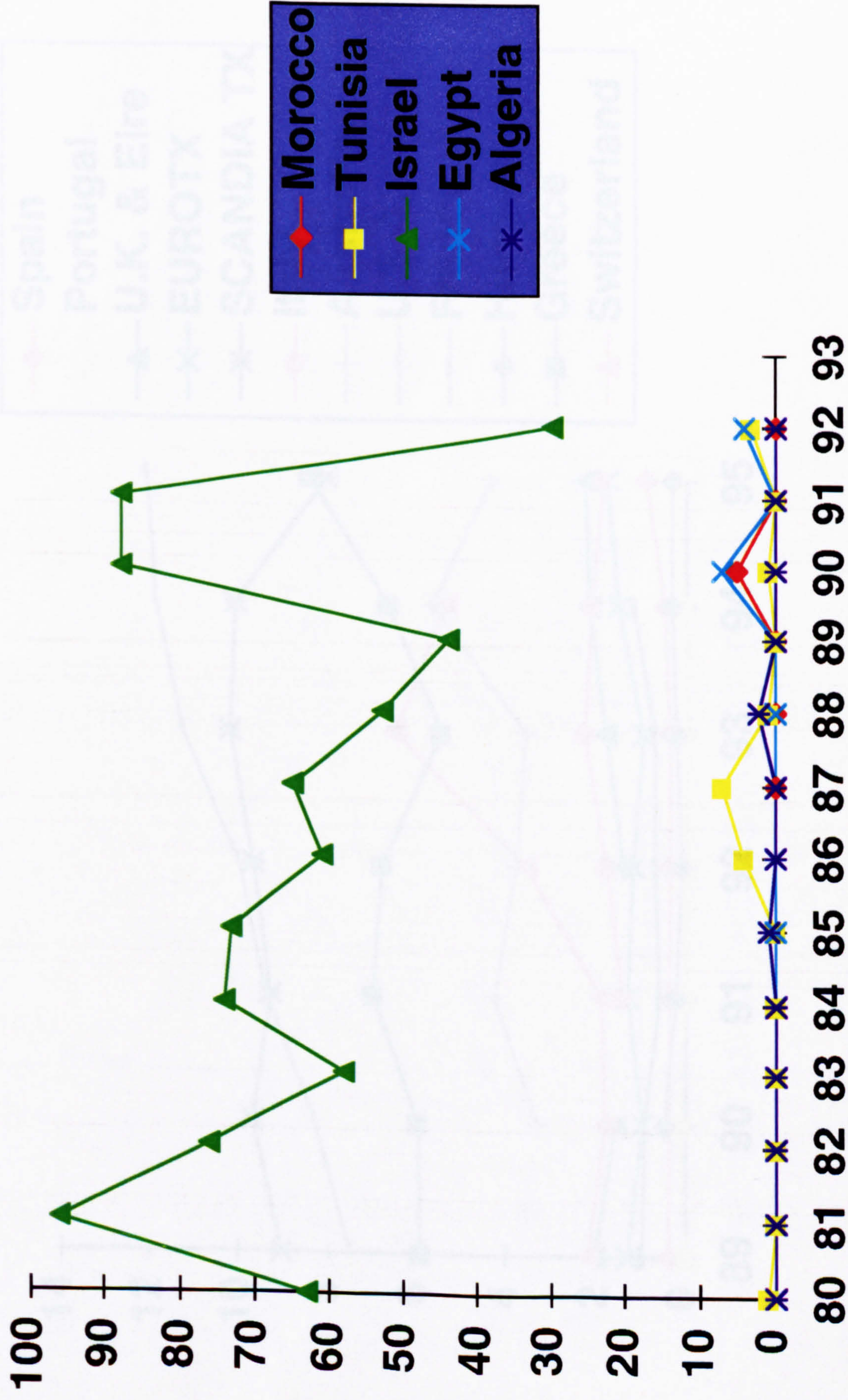


**Graph 24: ANNUAL CADAVERIC TRANSPLANTS IN FORMER  
CENTRAL AND EASTERN EUROPE.**



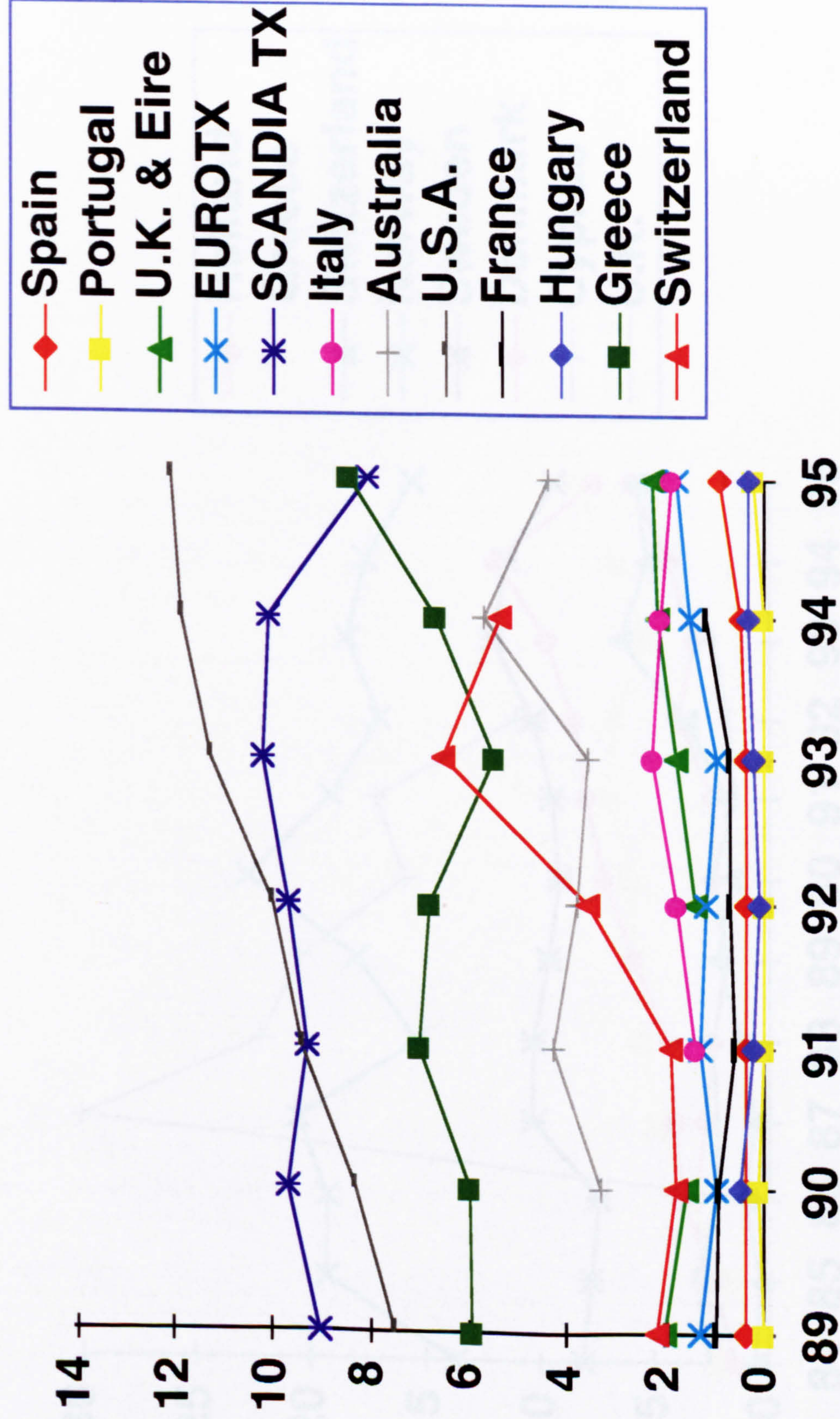


**Figure 25: ANNUAL CADAVERIC TRANSPLANTS IN EDTA  
NORTH AFRICAN / MIDDLE EASTERN COUNTRIES.**



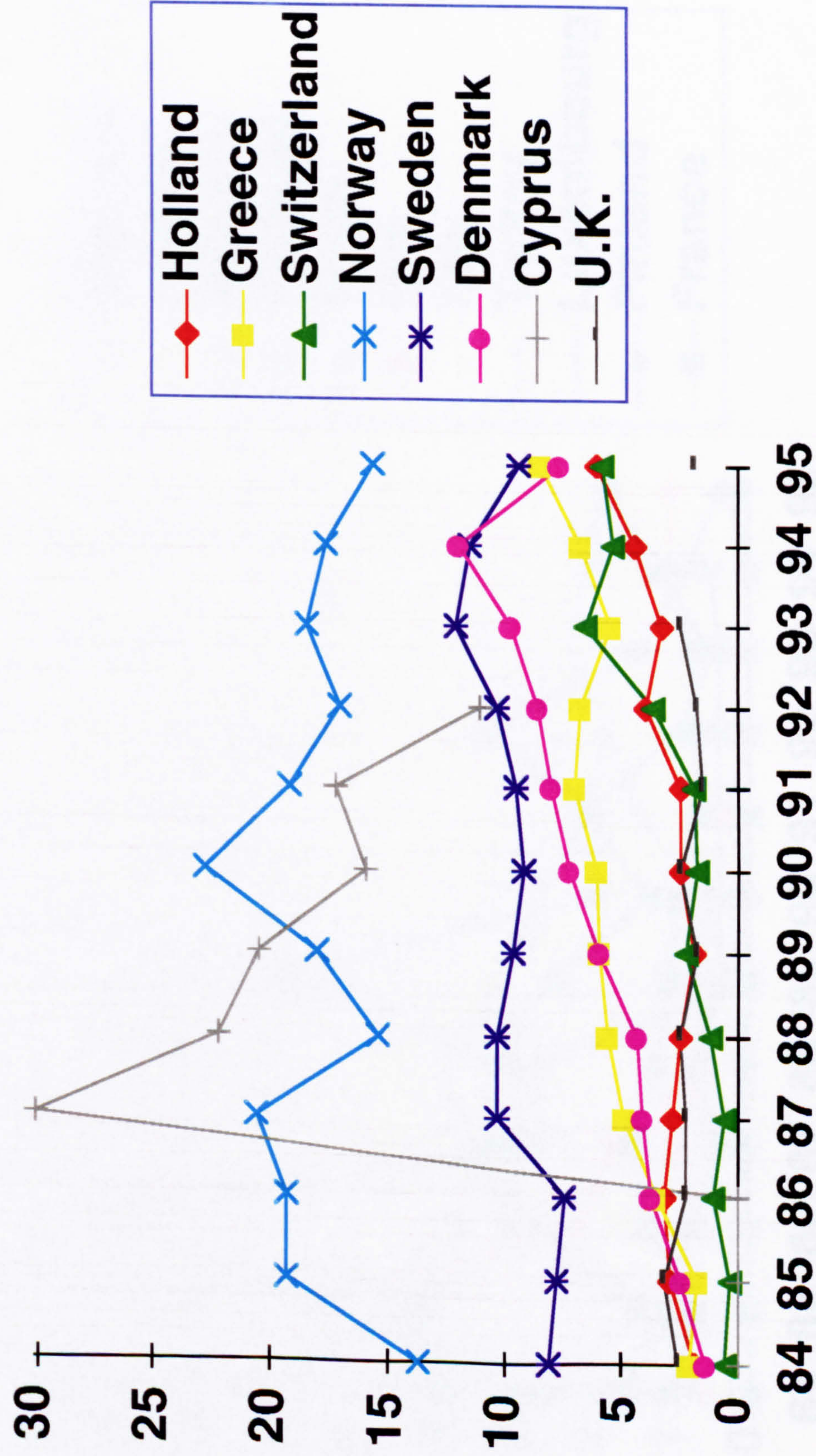


**Graph 26: LDT KIDNEY TRANSPLANTS PMP ANNUALLY IN SOME MAJOR TRANSPLANT AREAS.**





**Graph 27: NUMBERS OF LIVING DONORS 2+ PMP PER ANNUM  
IN WESTERN EUROPEAN COUNTRIES.**

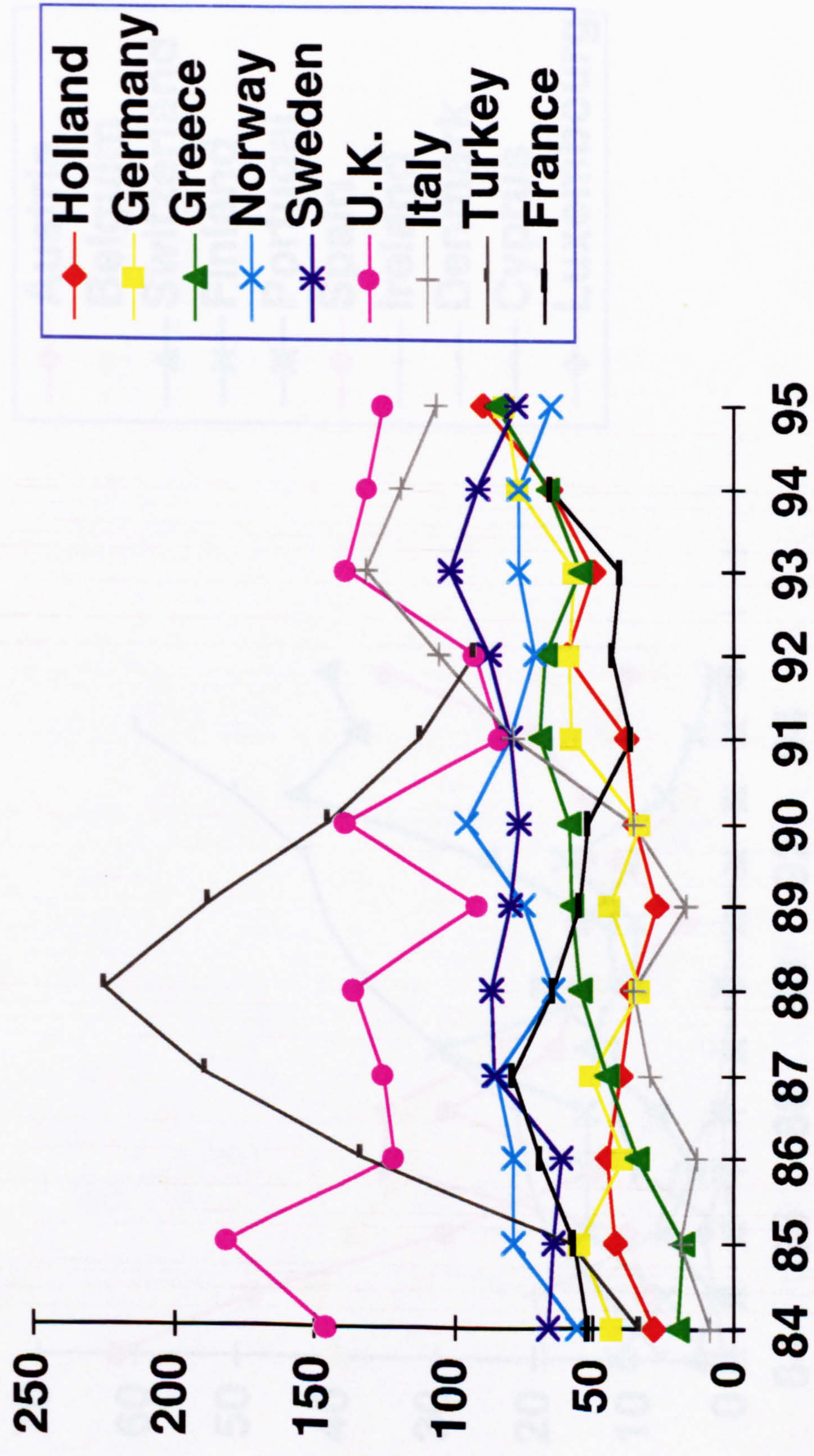






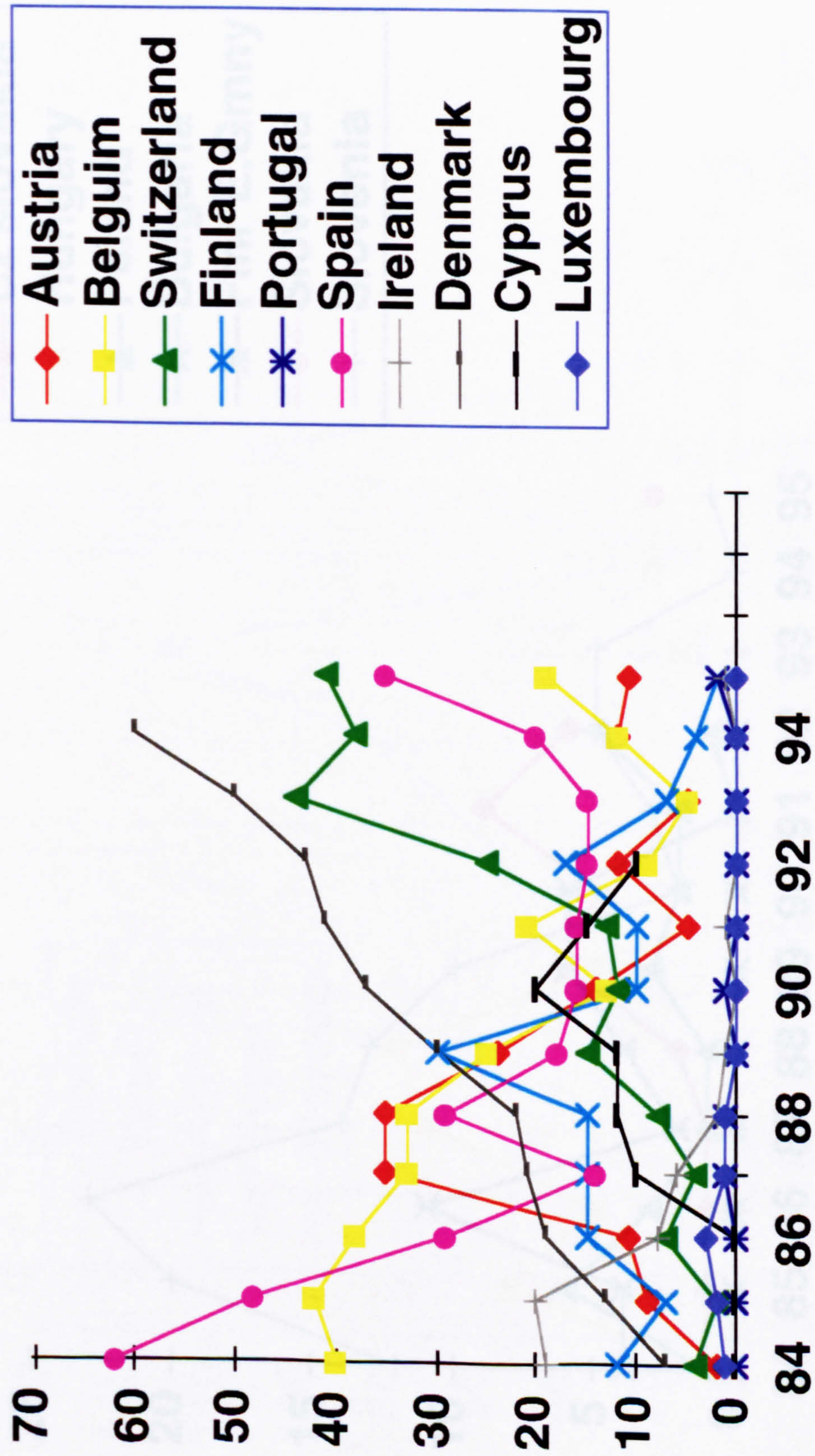


**Graph 29: NUMBERS OF LIVING KIDNEY DONORS 50+ ANNUALLY IN WESTERN EUROPEAN COUNTRIES.**



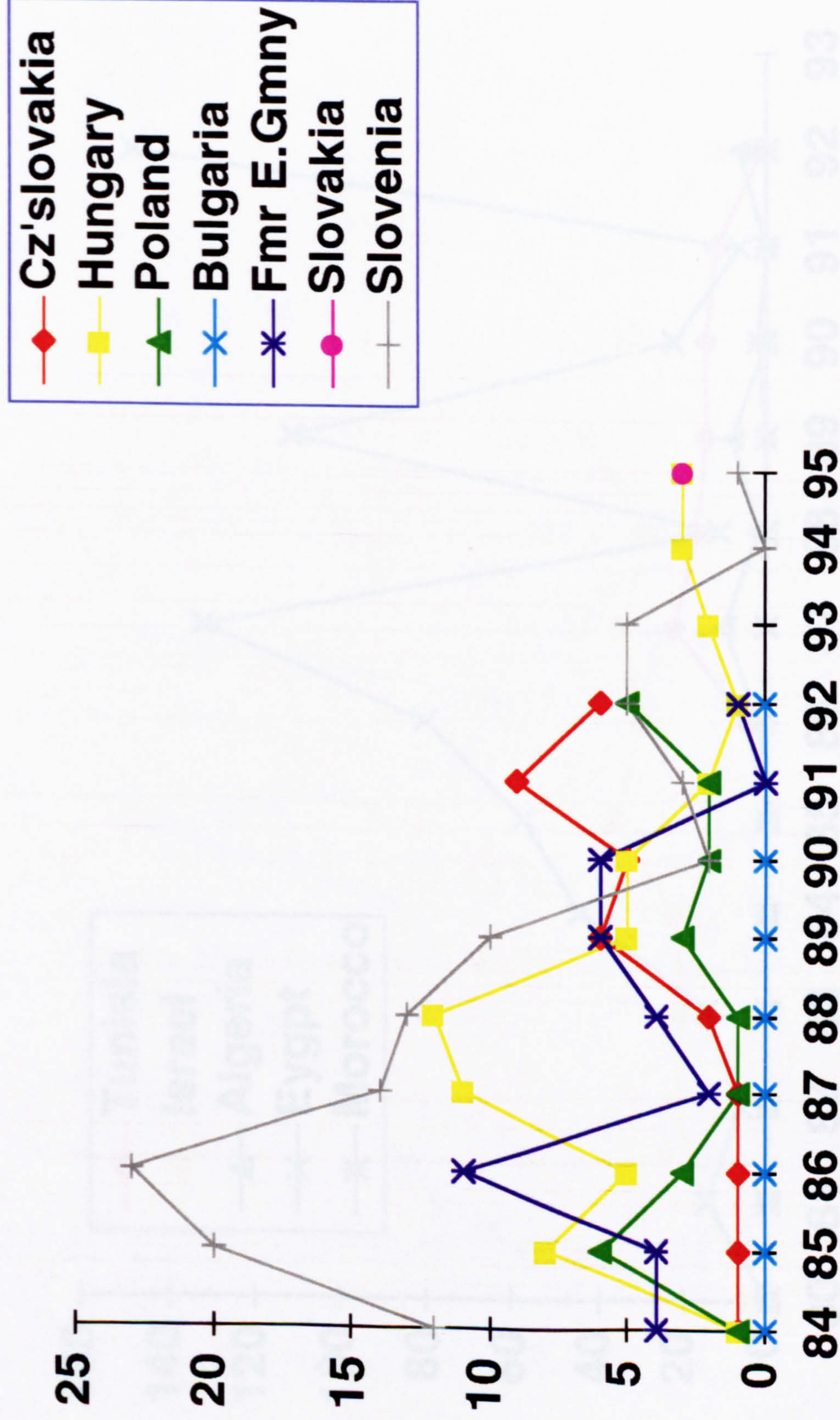


**Graph 30: NUMBERS OF LIVING KIDNEY DONORS BELOW 50 ANNUALLY IN WESTERN EUROPEAN COUNTRIES.**



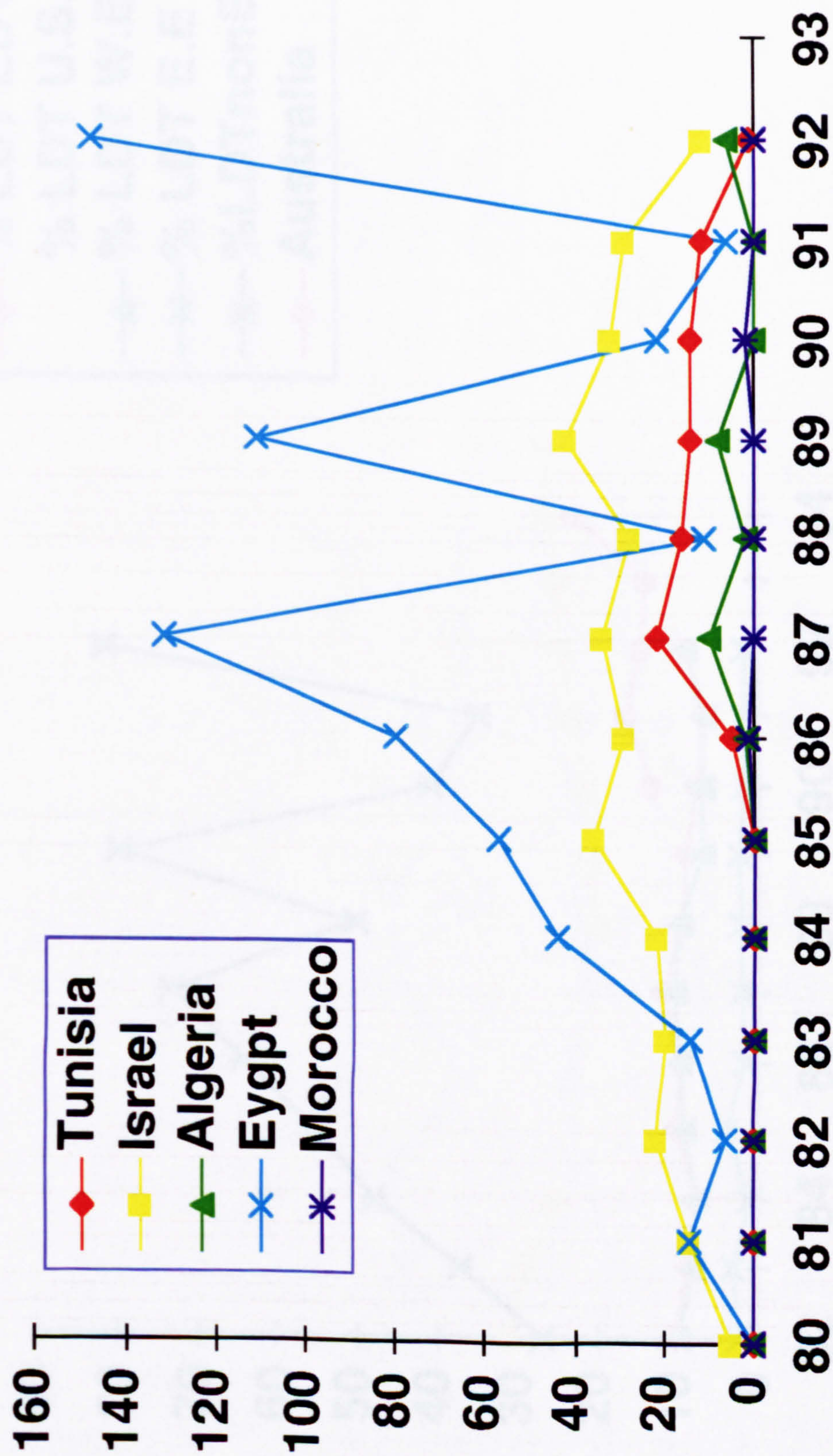


**Graph 31: ANNUAL NUMBERS OF LIVING KIDNEY DONORS IN  
FORMER EASTERN AND CENTRAL EUROPE.**



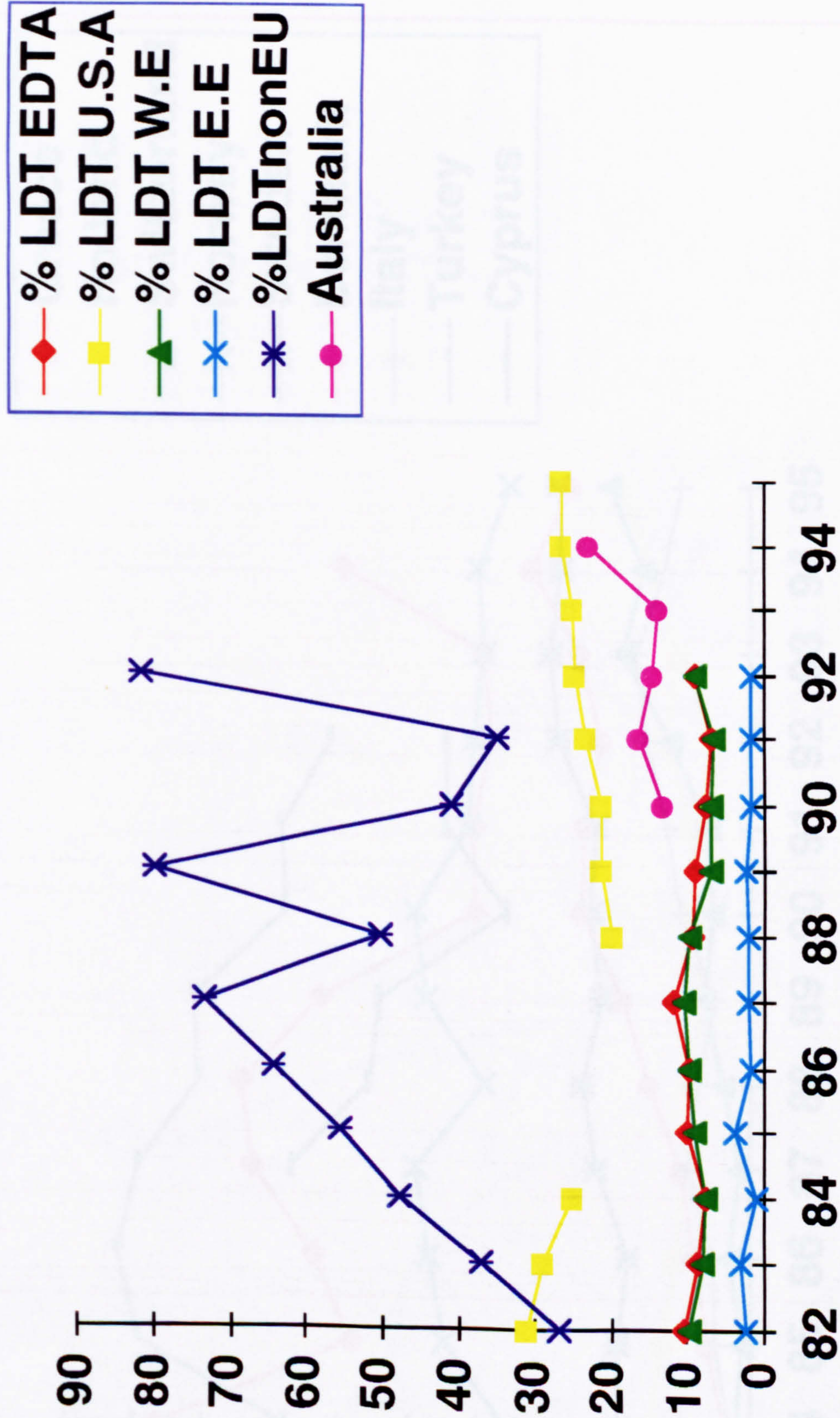


**Graph 32: ANNUAL NUMBERS OF LIVING DONORS IN NORTH AFRICAN AND MIDDLE EASTERN EDTA COUNTRIES.**



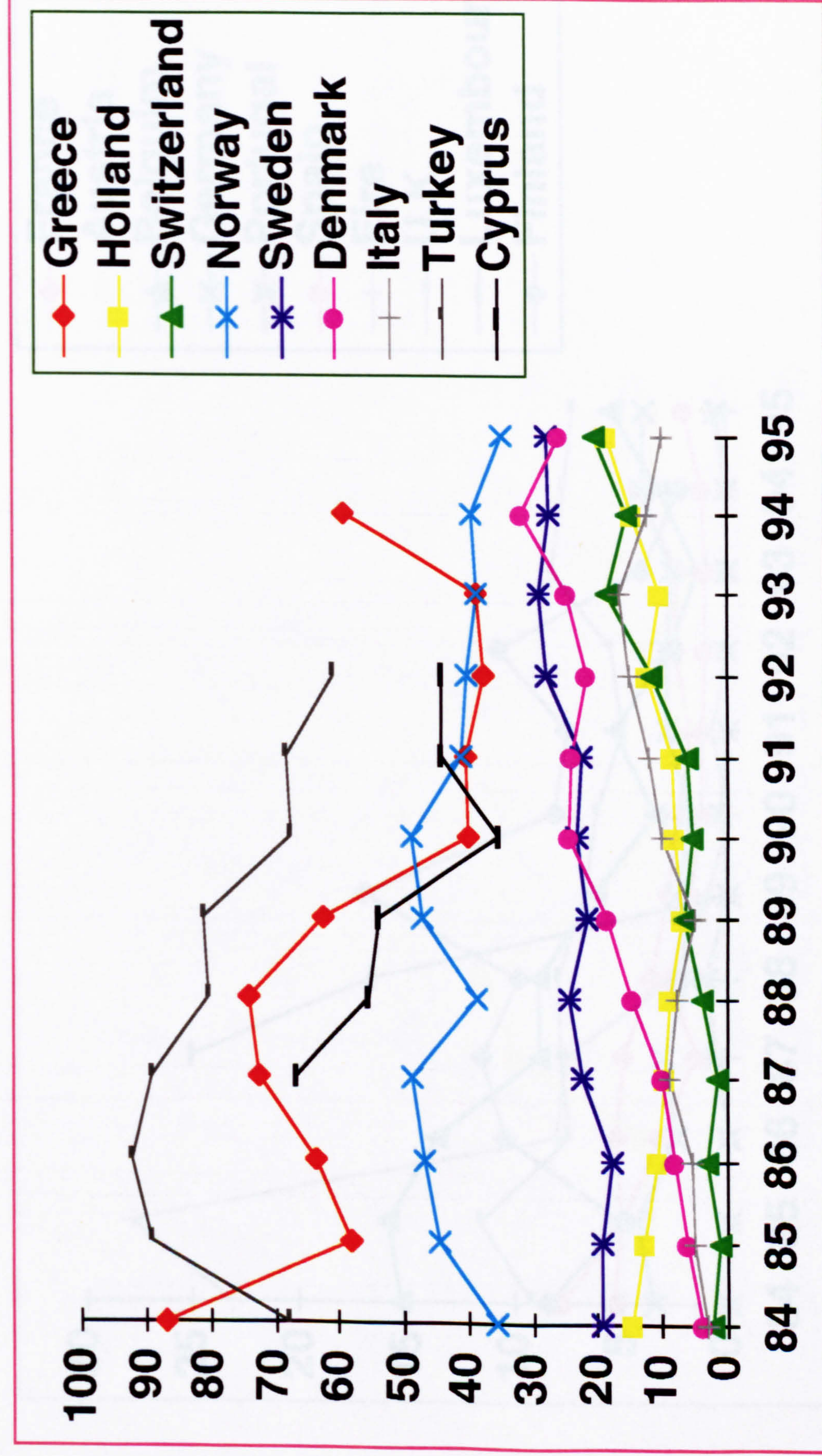


**Graph 33: %AGE LDT USE IN KIDNEY TRNSPLANTATION IN  
CENTRAL / EASTERN AND WESTERN EUROPE, NON  
EUROPEAN EDTA COUNTRIES, AUSTRALIA AND USA.**





**Graph 34: %AGE OF LDT'S IN ALL RENAL TRANSPLANTS  
ANNUALLY IN WESTERN EUROPEAN COUNTRIES ABOVE 10%.**

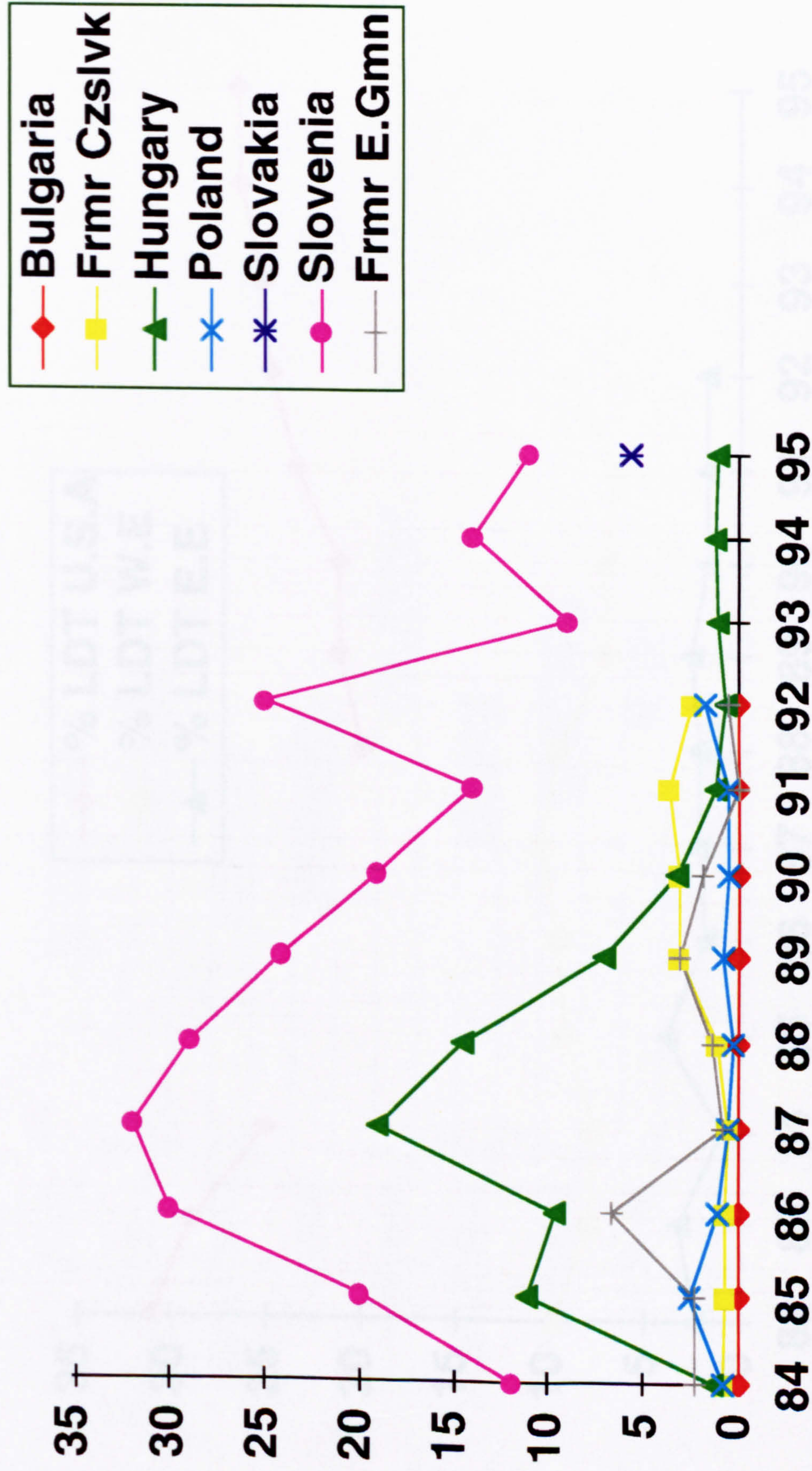






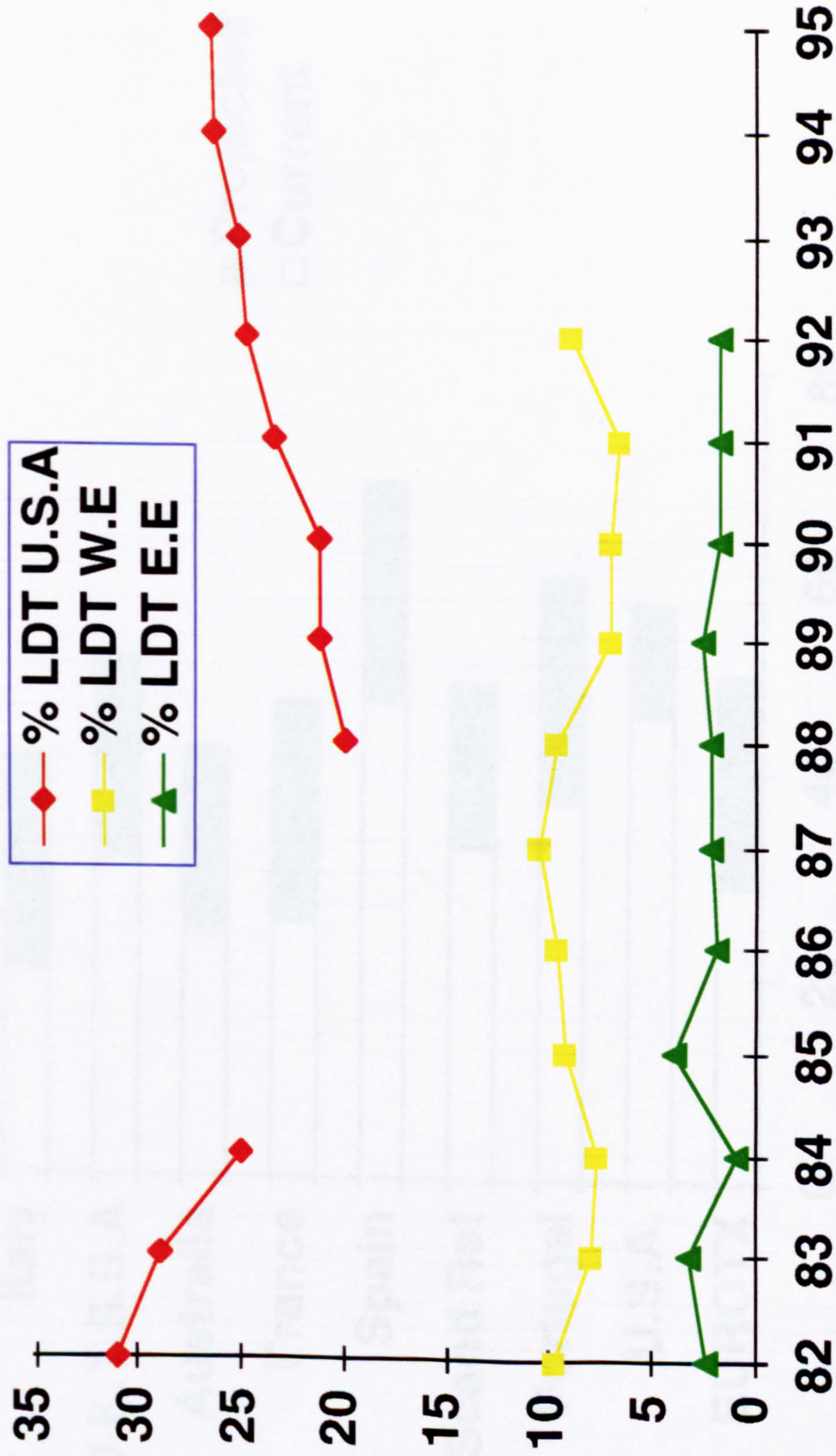


**Graph 36: %AGE OF LDT'S IN ALL RENAL TRANSPLANTS  
ANNUALLY IN FORMER CENTRAL AND EASTERN EUROPE.**



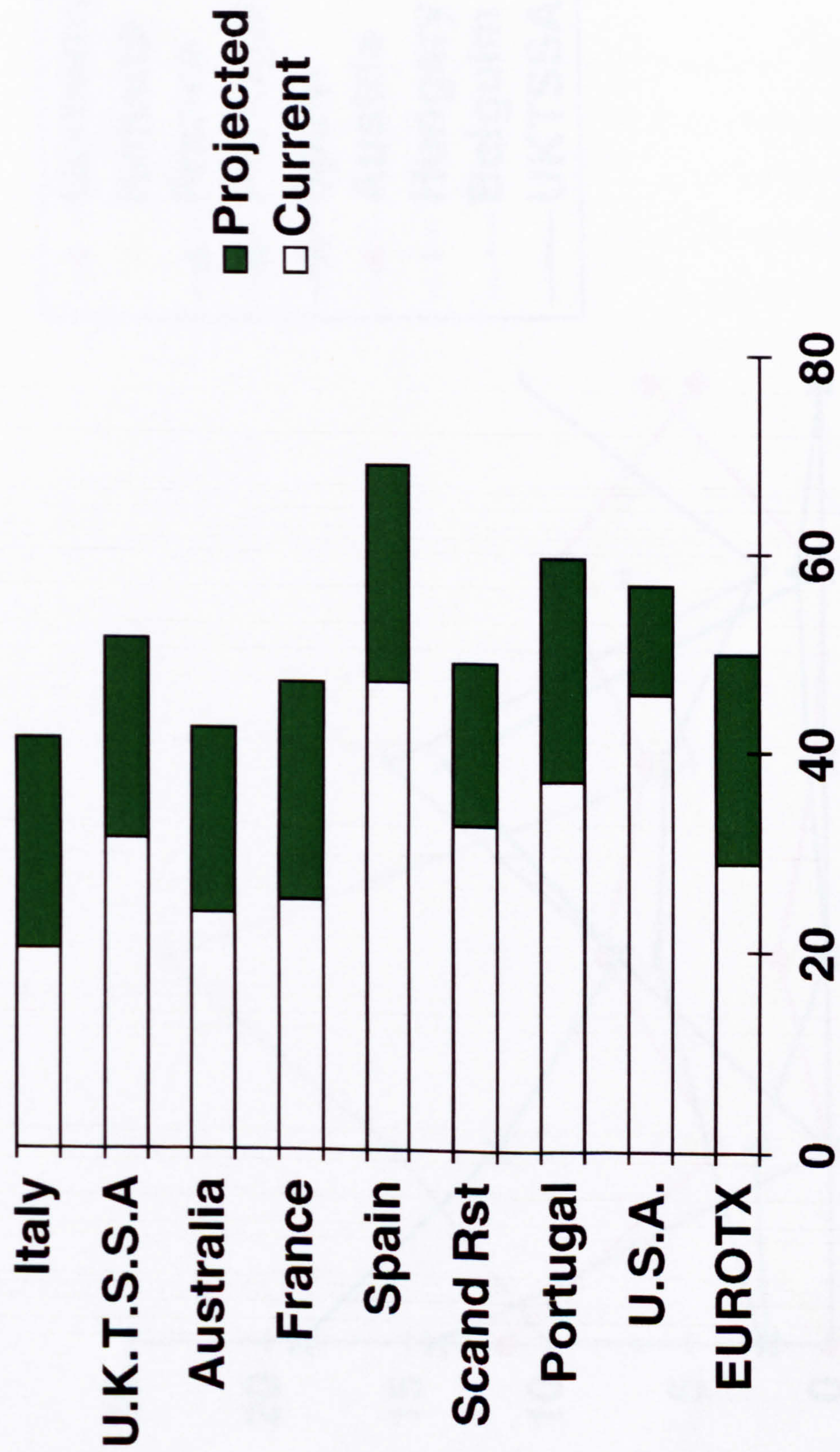


**Graph 37: %AGE USE OF LIVING DONORS IN FORMER  
CENTRAL / EASTERN, WESTERN EUROPE AND USA.**



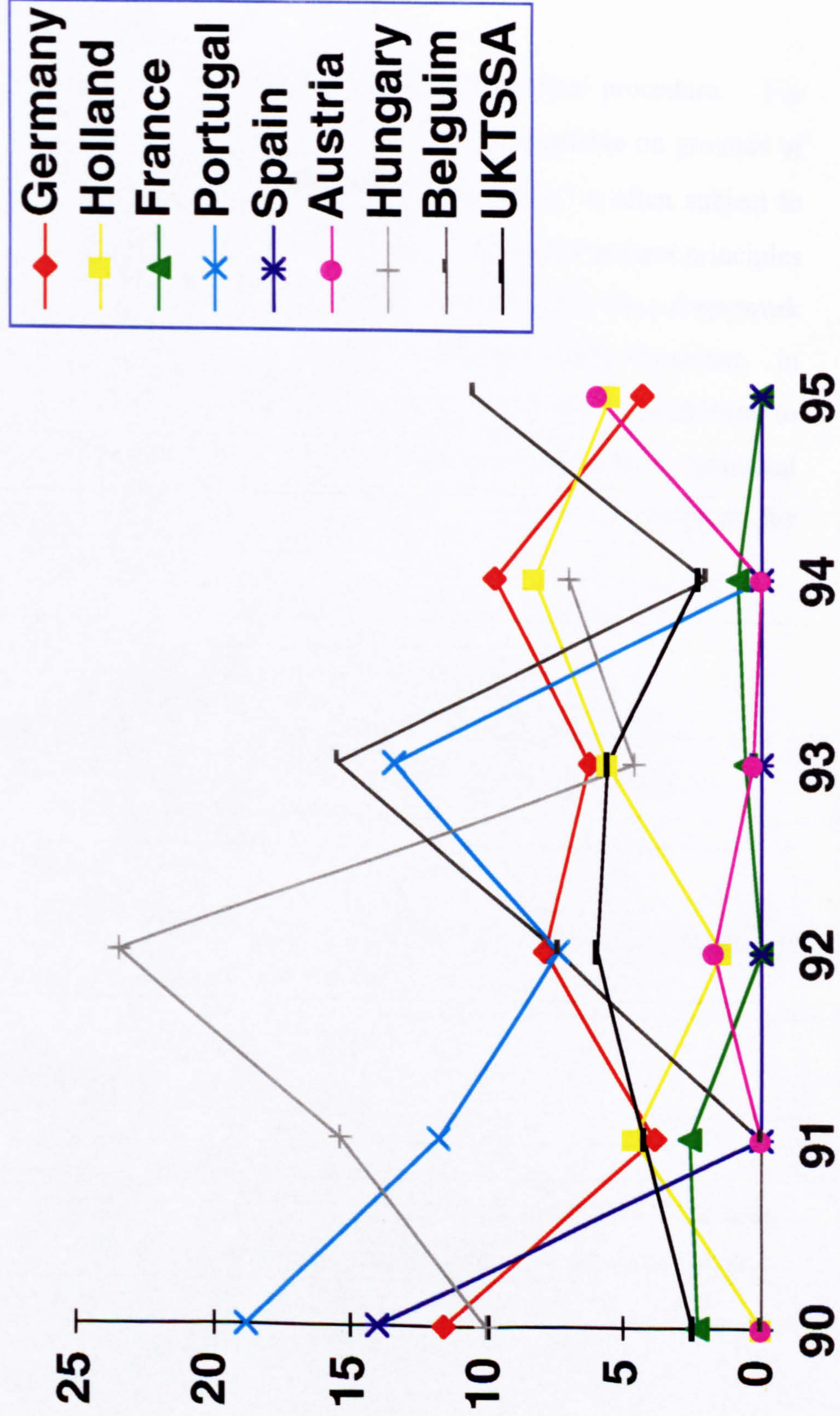


**Graph 38: PROJECTED IMPACT OF ADOPTING NORWEGIAN  
HIGHEST LDT RATE OF 22.8PMP IN 1990 ON OVERALL  
TRANSPLANT RATE PMP OF MAJOR TRANSPLANT AREAS IN  
1995.**





**Graph 39: 1990-1995 Increases in LDT p.m.p needed to match increases in waiting list sizes in Some Major European Transplant Countries.**





## **Chapter 4 Legality of LDT and Basic Legal Preconditions for Conducting it.**

### **4.1. Introduction**

There are basic legal pre-conditions for conducting any type of medical procedure. For instance, common law will always require that a procedure is acceptable on grounds of public policy. As with several serious medical procedures, LDT is often subject to legislative pre-conditions on its use which supplant and/or supplement general principles of law. Legislative stipulations in this area are partly designed to provide a framework for acceptable use of LDT by practitioners - such a framework being important, in particular, to protect prospective donors (prospective donors are generally considered to be in a vulnerable situation through being 'placed' in the position of being potential rescuers in a procedure not designed for their benefit). Basic preconditions for conducting LDT can be divided into 4 areas:

1. conditions as to the rationale for choosing living donation;
2. conditions as to the minimum acceptable prospective benefit-detriment ratio;
3. limits on allowable prospective (definite and potential) donor detriment; *and*
4. conditions as to the procedures that must be followed.

Of course before examining these issues in turn it is important to consider the legality of LDT.

### **4.2. The Legality of LDT.**

In most countries the legality of LDT in general is assured through legislation. At least before such legislation became commonplace there were questions as to whether LDT was legal because it involves mutilation without any direct therapeutic benefit for the donor. The issue of limits to the detriment that a person can legally endure was examined in English law in the case of R v Donovan [1934] 2 KB 498. This case laid



down the clear principle that limits exist. However, what has subsequently become clear, is that limits are not so much absolute as relative to the context and activity taking place. The key issue for judges has been whether or not enduring the detriment is, in the circumstances, in the public interest. As Lord Lane CJ said when giving the judgement in A-G's Reference (No. 6 of 1980) (1981) 2 All ER 1057,

"...Ordinarily, then, if the victim consents, the assailant is not guilty...The question is: at what point does public interest require the court to hold otherwise? ...The answer to this question, in our judgement, is that it is not in the public interest that people should try to cause or should cause each other bodily harm for no good reason."<sup>1</sup>

However, whether the judges have taken a consistent approach to this issue is debatable. On the one hand, some activities that can be viewed as causing significant pointless or at least unnecessary self-harm have been declared legal, the most obvious example being boxing.<sup>2</sup> Other acts tending to cause less harm can be declared outside the legal limits of what can be consented to - hence in R v Brown (Anthony) [1993] 2 All ER 75, [1994] 2 WLR 556 the House of Lords declared certain acts of sexual sado-masochism to be outside of the boundaries of law.<sup>3</sup> What is clear is that *reasonable* surgical interference has long been assumed to be legal.<sup>4</sup> Recently in Airedale NHS Trust v Bland [1993] 1 All ER 821 Lord Mustill explicitly stated that,

"bodily invasions in the course of proper medical treatment stand completely outside the criminal law."<sup>5</sup>

The problem is that the normal justification for surgical interference, that it is in the patients best interests, cannot easily apply to LDT. In practice physically non-

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<sup>1</sup>[1981] 2 ALL ER 1057.

<sup>2</sup>Although not where done with bare knuckles R v Coney [1882] 8 QBD 534.

<sup>3</sup>For a critique of this judgement see E Edwards, 'No Defence for a Sado-Masochistic Libido,' *NLJ*, 1993, 143, 552.

<sup>4</sup>See e.g. A-G's Reference (No. 6 of 1980) (1981) 2 All ER 1057.

<sup>5</sup>[1993] 1 All ER 821 at 889.



therapeutic procedures have been declared illegal or legal depending on the public interest in the circumstances. Hence, while it is normally legal to perform a sex change operation (Corbett v Corbett (otherwise Ashley) [1970] 2 All ER 33 per Ormrod J<sup>6</sup>) it is illegal to engage to engage in the mutilation of female genitalia.<sup>7</sup> A key is whether the overall intention of the procedure can be regarded as beneficial or "reasonable."<sup>8</sup> Genital mutilation may be regarded as something that women are often unduly influenced, 'brainwashed' or coerced into and is specifically designed to reduce sexual pleasure. It could be regarded as oppressive and not worthy of public support. A sex change on the other hand is someone's individual choice about their sexual identity. Normally it is a free decision made without coercion or undue influence. It causes physical harm but this is accepted as incidental to its main purpose. Even if some people challenge the rationality of the procedure there is no basis for claiming it is actively against the public interest. Living organ donation goes beyond an ordinary physiologically non-therapeutic procedure because (unlike, for instance, a sex change operation) its purpose is normally not any kind of benefit to the person undergoing it but solely the benefit of another. The reason why judges, in cases where donation of an organ or tissues is examined, have assumed that LDT can be legal<sup>9</sup> is presumably that it has a reasonable and beneficial purpose rather than an oppressive one and can therefore be in the public interest. The donor in effect is an 'approved rescuer.' Rescuers have traditionally been given legal protection and praise rather than their actions being declared unlawful or illegal.<sup>10</sup> The key to the prospective donor being allowed to

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<sup>6</sup>[1970] 2 All ER 33 at 43.

<sup>7</sup>The Prohibition of Female Circumcision Act 1985 under which physically non-therapeutic procedures involving mutilation of the clitoris, labia etc. are illegal, being clearly in this instance against the public interest. Mutilation would probably have been illegal at common law also.

<sup>8</sup>A view expressed by Lord Lane in Attorney-General's Reference [No.6 of 1980][1981] 2 All E.R. 1057 CA as confirmed in Brown on this point.

<sup>9</sup>See chapters 5-7 for cases where LDT is discussed obiter or is the matter at hand. Skegg has said, "if called upon to deal with a case in which a kidney had been removed from a consenting adult, for transplantation into someone in need of it, the courts may confidently be expected to take the view that the operation did not amount to the offence of battery" (Law, Ethics and Medicine: Studies in Medical Law, Clarendon Press 1988 at 36).

<sup>10</sup>See for instance Haynes v Harwood [1935] 1 KB 146 (CA) duty of care owed to the rescuer by person being rescued where rescue might reasonably have been foreseen. Videan v British Transport Commission [1963] 2 QB 650, [1963] 2 All ER 860 (CA) duty of care owed to a stationmaster rescuing his small son who had been trespassing on the lines. Street states that the rescue cases in England, "are marked by an emphatic desire by the judiciary to 'reward' desirable conduct and encourage in this limited sphere 'Good



engage in the rescue act is generally that what (s)he is doing has a level of benefit to another without an excessive or overriding level of detriment to him/herself *although*, as examined in chapter 7, matters are not so simple as this where the donor is a minor or incapacitate adult.

An interesting final point is Michielson's questioning of the legality of LDT on the basis that problems in assessing risks make informed consent to organ LDT impossible.<sup>11</sup> This view must be rejected because the reality of almost any medical decision, indeed any decision in general, is that it will carry an element of uncertainty in terms of knowledge of risks and consequences. This uncertainty is not held to invalidate consent legally<sup>12</sup> and ethically it will normally be acceptable just to convey any significant areas of uncertainty.

#### **4.3. Legal Preconditions as to the Basic Rationale for Choosing LDT.**

Transplantation is considered the 'ultimum remedium' to be used where there are no other reasonable alternatives and is generally only allowed for therapeutic, not purely scientific, purposes.<sup>13</sup> This approach is philosophically underpinned by the principle of *primum non nocere* (first do no harm). Despite its side effects modern allopathic medical treatment is generally accepted as capable of respecting this principle where the procedure is, all things considered, in the best interests of the patient. However, living donors can gain only vicarious benefit from donation along with some direct physical detriment. Nys concludes that if *primum non nocere* is to be taken seriously,

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Samaritanship" (Street On Torts, Eighth Edition edited by Margaret Brazier, *Butterworths*, 1988 at 176). This quote could just as easily be applied by judges to LDT.

<sup>11</sup>P.Michielson, Medical Risk and Benefit in Renal Donors: The Use of Living Donation Reconsidered, in W.Land and J.Dossetor (eds.), *Organ Replacement Therapy: Ethics, Justice and Commerce*, 1990, Springer-Verlag, 32-39.

<sup>12</sup>The Voluntarism and Informedness of Living Donors in Price and Akveld (eds.), *Living Organ Donation in The Nineties: European Medico-Legal Perspectives*, *EUROTOLD*, 1996, 98-115 at 99.

<sup>13</sup>Excepting transplantation between animals.



"it follows .. that organs that may be removed from living donors will always be limited. Organs that are not only not regenerative but are also vital such as heart and liver cannot be removed."<sup>14</sup>

It would also follow from the *primum non nocere* principle that preconditions should rightly exist for preferring living donation to other options.<sup>15</sup> General legal principles are unlikely to give direct attention to this issue and neither does the Council of Europe's Resolution (78)29. However, the WHO Guiding Principles on transplantation state that organs should preferably come from the bodies of deceased persons<sup>16</sup> and, as illustrated below, transplant legislation typically has preconditions for favouring LDT - partly to ensure that there is an adequate rationale for conducting it.

#### **4.3.1. Rationale for Transplantation Generally as the Optimum Remedium or Last Resort.**

Some laws require transplant to be the optimum solution under the circumstances or even a last resort. This is really only a requirement that reflects the physicians Hippocratic to act in the patients best interests and not engage in a harmful procedure unless absolutely necessary. Regimes with this requirement include: Belarus (draft),<sup>17</sup> Belgium,<sup>18</sup> Finland,<sup>19</sup> GDR,<sup>20</sup> Russian Federation<sup>21</sup> and Ecuador<sup>22</sup> where the patient must be

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<sup>14</sup>Of course this should not preclude removal of these organs for therapeutic purposes and living donation as a merely incidental fact to this (e.g. domino heart procedure). See Nys, *Desirable Characteristics of Living Donation Transplant Legislation in Living Organ Donation in the Nineties: European Medico-Legal Perspective*, (Ed D.Price and H.Akveld), *EUROTOLD*, 1996, 116-125.

<sup>15</sup>E.g. CDT or dialysis.

<sup>16</sup>Guiding Principle 1 - see chapter 7 for more detailed comment on these principles.

<sup>17</sup>States that the transplantation of organs and tissues, "may be effected only if other medical procedures would not enable the patient's life to be safeguarded or his health to be restored...(and) shall be carried out on the basis of medical indications, in accordance with the general rules applicable to surgical procedures." Section 4 of the Draft Law of the Republic of Belarus on the Donation and Transplantation of Human Organs and Tissues - copies available from WHO or the EUROTOLD project.

<sup>18</sup>Law No. 32 of 13 June 1986 On the Removal and Transplantation of Organs at section 6.

<sup>19</sup>Law No. 355 of 26 April 1985 On the Removal of Human Organs and Tissues for Medical Purposes at section 2.

<sup>20</sup>This states, "it shall be a prerequisite for organ transplantation that there are no or only limited prospects of successful results being achieved through the application of other medical procedures and methods for the preservation of life or the restoration or improvement of the health of the patient" (law operating in the



suffering from a disease for which the transplant is the only means of prolonging or improving his life;<sup>23</sup> Algeria<sup>24</sup> and Romania<sup>25</sup> where the transplant must be the sole means of preserving the life or physical integrity of the recipient.

Dialysis might be perceived as capable of improving health or at least preserving physical integrity, in which case most of these provisions would restrict transplant to exceptional cases. There was not much foresight in the drafting of these provisions! However, common sense may prevail to allow LDT to be conducted where it was the means to preserve / improve existing quality of life *in terms of the long-term prognosis*. Russian Federation law is well framed by ignoring health preservation and stating that transplantation may only be carried out where other medical techniques cannot guarantee the saving of the life of the patient or the restoration of health.<sup>26</sup>

#### **4.3.2. Legislative Preference for CDT and the Explicit Legislative Requirement that LDT is the Optimum Remedium.**

Some jurisdictions have a regulatory bias towards CDT. Swedish law states that the use of living donors should be limited as much as possible<sup>27</sup> Colombian law requires that the living organ donation to be for a therapeutically indispensable transplantation<sup>28</sup>

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5 new Landers of Germany that used to be East Germany. Ordinance of 4th July 1975 On The Performance of Organ Transplantation section 1(3)).

<sup>21</sup>Law of 22 December 1992 of the Russian Federation On the Transplantation of Human Organs and/or Tissues at section 1.

<sup>22</sup>Law No. 64 of 26 May 1987 Reforming the Health Code at section 2.

<sup>23</sup>Ecuador also has the de minimus requirement that the patient have sufficient health to sustain surgery and post operative treatment.

<sup>24</sup>Law No. 85-05 of 16 February 1985 On Health Protection and Promotion at section 166.

<sup>25</sup>Law of 1996 (available from EUROTOLD).

<sup>26</sup>Law of 22 December 1992 of the Russian Federation On the Transplantation of Human Organs and/or Tissues at section 1.

<sup>27</sup>Explanatory Memorandum to the new Act of 8 June 1995 On Transplantation etc. - see Linda Nielson, Living Organ Donors: Legal Perspectives From Western Europe in D.Price and H.Akveld (ed.), Living Organ Donation in the Nineties: European Medico-Legal Perspectives, *EUROTOLD*, 1996, 58-71. This represents a slight change in approach given that Sweden's old law allowed very unfettered clinical judgement by simply requiring that the transplant is to treat a disease or physical injury in another person (The Transplantation Law (No. 190) of 15 May 1975 at section 1).

<sup>28</sup>Decree No. 1172 of 6 June 1989 at section 24.



implying that cadaveric donation would be given prior consideration over LDT, with the latter only able to be used if really necessary. Slovenian law<sup>29</sup> requires living donation to be the best therapeutic solution for the recipient and cadaveric is to be preferred where there is reasonable availability. In contrast to these straightforward provisions, Belgian and Mexican regulation is fraught with ambiguity in this area.

In Belgium the law states that,

"if the removal of organs or tissues from living persons may affect the donor, or if such organs are non-regenerable, it may only be performed if the recipient's life is in danger and if the transplantation of organs or tissues from a deceased person could not produce an equally satisfactory result"<sup>30</sup>

Herman Nys, a Belgian legal academic, assumes "life in danger" to mean anywhere where renal failure has occurred.<sup>31</sup> This broad interpretation avoids the farcical situation of only allowing LDT where there is immediate danger to life.<sup>32</sup> Another aspect of Belgian law is that LDT is only permitted insofar as the use of a cadaveric organ does not offer prospects of an "equally satisfactory result."<sup>33</sup> This stipulation is, in effect saying that because LDT causes the donor some detriment it must be justified as being a better option than CDT in the circumstances. Mexican law goes even further, stating that LDT may only occur when organs or tissues from cadavers *cannot* be used.<sup>34</sup>

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<sup>29</sup>Article 2 *ibid*.

<sup>30</sup>Law No. 32 of 13 June 1986 On the Removal and Transplantation of Organs at section 6.

<sup>31</sup>Nys comments that if the transplantation were not to preserve life and was for a futile transplantation it would breach Article 2 of the European Convention of Human Rights which emphasises the duty of the state to preserve life (Desirable Characteristics of Living Donor Transplant Laws in D.Price and H.Akveld (ed.), *Living Organ Donation in the Nineties: European Medico-Legal Perspectives*, *EUROTOLD*, 1996, 114-124).

<sup>32</sup>This would exclude the majority of patients who are surviving reasonably on dialysis and shackle LDT from being used at an optimal time when the patient is most healthy (i.e. pre-dialysis or early dialysis basis).

<sup>33</sup>Article 6 of 1983 law. This position is recommended by B.Schoeller, *Vorschlag Fur Eine Gesetzliche Regelung der Organspende Vom Lebender Spender* (proposal for an LDT law for Germany), *Peter Lange* 1993 at 78.

<sup>34</sup>The General Law on Health 26 December 1983 at section 322. Mexican law also requires the recipient to be suffering from an ailment which can be effectively treated by means of the transplant and is not suffering from other diseases which could foreseeable jeopardise the success of the transplant (Federal Regulation of 16 August 1976 On the Use of Human Organs, Tissues and Cadavers at section 35).



Nys has noted interpretational problems in the Belgian provision,

"Should this requirement be understood 'in abstracto', which means that transplantation with a cadaveric does not offer, as a rule, similar results as transplantation with a living donated organ, or 'in concreto', which means that if no cadaveric organ is available in a given case the condition is fulfilled. But what is the meaning of 'not available'? In the region? The country? Europe? Worldwide?"<sup>35</sup>

Hopefully common sense would prevail in interpreting the provision as requiring the clinician to make a reasonable assessment of whether or not LDT is better than cadaveric in the light of the individual case circumstances. Main factors to weigh would be: the level of match of the proposed LDT; the level of urgency of the need of the recipient; and likely cadaveric waiting time for the recipient. For instance, if the expected waiting time was 3 years and the proposed living donor was a good match an LDT would probably be justified as better. If expected waiting time was less than a year probably only exceptional recipient need and / or a perfect match would justify LDT as more satisfactory (a similar situation and policy to this exists in Eire at present).

The requirement in Mexican law that LDT can only be used when CDT '*cannot*' be used is somewhat bizarre and unreasonable as it stands. Even if *cannot* is taken as referring to a cadaveric organ not being obtainable within a reasonable period of time the provision is restrictive and in need of amendment. Perhaps a new provision could say that LDT is permissible where a reasonable cadaveric organ is *unlikely* to be found within a reasonable time period.

Ambiguity and uncertainty of the Belgian and Mexican variety may produce a disinclination amongst professionals to use LDT; indeed, for example, the attitudes questionnaire results presented in chapter 10 indicate that some Belgian transplant

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<sup>35</sup>Desirable Characteristics of LDT Legislation - *ibid*.



professionals wrongly think LDT is *illegal*. The underlying principle of requiring LDT to be superior to cadaveric donation is valid - in so far as it protects healthy volunteers from the extreme utilitarianism of being used as 'waiting list reducers' when a cadaveric donation would have been as successful. On the other hand whether people want to be used in this way could be viewed as their business; they simply need to be clearly told and left to decide whether or not they want to engage in an act of such 'social solidarity'.<sup>36</sup>

Other provisions require LDT's to be the best available choice in the circumstances which would include being superior to the cadaveric option. For instance, Argentina's law states that LDT is to be used where, "other means have been exhausted or are insufficient, or if they do not constitute an appropriate therapeutic solution for a particular patient."<sup>37</sup> Peruvian law<sup>38</sup> requires LDT to be the best therapeutic solution for the recipient. The authorisation process for LDT in the Canadian model law considers whether it is the treatment of choice.<sup>39</sup>

#### **4.3.3. Justification for Transplantation in Terms of Anticipated Results.**

When is it justified to conduct transplantation? This is usually left for clinicians to decide. Polish law is an example of legislation reinforcing clinical discretion. It requires the doctor performing the transplantation to determine the justification and expediency of harvesting cells, tissues and organs from a particular donor.

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<sup>36</sup>A Norwegian donor gifted partly for this explicit reason (see chapter 9).

<sup>37</sup>Law No. 24193 of 24 March 1993 On the Transplantation of Organs and Anatomical Materials at section 2 (taken from *IDHL*, 1994, 45(1), 35-36). Additionally where living donation is specifically proposed it must, "offer the likelihood of success with regard to preserving the life or improving the health of the recipient" (section 14). The old law stated that LDT's should be considered "as standard procedures rather than experimental ones, which may be performed when all other available non-artificial means and resources have been exhausted and there is no alternative therapeutic means of restoring the patient's health" (Law No. 21541 of 21 March 1977 On the Removal and Transplantation of Organs and Anatomical Materials at section 2). The need to use non-artificial means and resources first may refer to nutritional therapy and other potentially more holistic treatments.

<sup>38</sup>Law No. 23415 of 1 June 1985 at section 7(a) repealed by Supreme Decree No. 014-88-SA of 19 May 1988 at section 14 (*IDHL*, 1994, 45(1) at 36-37).

<sup>39</sup>Uniform Human Tissue Donation Act 1990 at section 5(3) and section 7((6)).



Transplantation to a specified recipient is determined on the basis of actual medical knowledge.<sup>40</sup>

Other legislative provision in this area tends to be de minimus in its level of stringency and tends to refer to transplantation as a whole. The former GDR law (in force in the 5 new Landers of Unified Germany) states that transplantation must only be conducted in situations where it, "may be assumed with a high degree of probability that transplantation of the organ will save the life or restore or improve the health of a patient."<sup>41</sup> Bolivian law allows for transplantation to maintain, restore and prolong human life;<sup>42</sup> a clinician would not normally do it on any other basis anyway. Paraguay's law requires that the transplant demonstrably prolongs or improves the recipients health.<sup>43</sup> Kuwaiti law simply requires the transplantation to be in order to protect or prolong life.<sup>44</sup> The only clinical restriction in France,<sup>45</sup> Panama,<sup>46</sup> Uruguay,<sup>47</sup> Tunisia,<sup>48</sup> Venezuela<sup>49</sup> and India<sup>50</sup> is that the removal is for therapeutic purposes. Iraq's law requires simply that the donation is for therapeutic purposes or where necessary to maintain life.<sup>51</sup>

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<sup>40</sup>Law of October 26, 1995 Regulating the Removal and Transplantation of Human Cells, Tissues and Organs at Article 9(1) point 3. Translated copy of the law held at EUROTOLD courtesy of the Polish PECO participants.

<sup>41</sup>Ordinance of 4th July 1975 (operative in the 5 new Landers of unified Germany that used to be East Germany) at section 6.

<sup>42</sup>Regulations On the Use of Organs and Tissues 15 March 1982 at section 1.

<sup>43</sup>Law No. 826180 of 15 December 1980 Promulgating the Health Code at section 278.

<sup>44</sup>Decree Law No. 55 of 20 December 1987 On Organ Transplantation at section 1.

<sup>45</sup>Law No. 94-54 of 29 July 1994 On the Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation, and Prenatal Diagnosis (*Journal Officiel de la Republique Francaise*, Lois et Decrets, 30 July 1994, 175, pp 11060-11068, Division 2, Article L. 671-3. See *IDHL*, 1994, 45(4), 473-482. at p474.

<sup>46</sup>Law No. 10 of 11 July 1983 Regulating the Transplantation of Organs and Anatomical Parts and Laying Down Other Provisions at section 1. Section 12 says that organs may be donated in order to preserve or restore the patients health.

<sup>47</sup>Decree No 660/991 of 4 December 1991 at section 1. Updating Regulations No. 86/977, made for the implementation of Law No. 14005, for the purpose of determining the technical supervision of the National Organ and Tissue Bank (*IDHL*, 1994, 45(1) at 38).

<sup>48</sup>Law No. 91-22 of 25 March 1991 On the Removal and Transplantation of Human Organs at section 2

<sup>49</sup>Law of 19 November 1992, No. 4497 at section 3 (implicit) (*IDHL*, 1995, 46(3) at 329-330.

<sup>50</sup>Act No. 42 of 1994 section 3 (*IDHL*, 1995, 46(1) at 34-37). Therapeutic purposes are defined in section 1 as "systematic treatment of any disease or the measures to improve health according to any particular method or modality."

<sup>51</sup>Decree No. 698 of 27 August 1986 of the Revolutionary Command Council at section 1.



#### **4.3.5. Justification in Terms of Biological Compatibility Between Living Donor and Recipient.**

Often, centre policy will require a certain level of biological compatibility between donor and recipient to conduct LDT. In bone marrow transplantation full compatibility is a basic clinical *necessity* but where organs are concerned the stipulation of certain levels of compatibility is aimed simply at *improving* the quality of transplant. In this light requirements can be seen as an indirect method for helping to ensure that LDT is sufficiently justified. At the same time such requirements are not flexible to the circumstances of justification in an individual case and do not of themselves ensure that an LDT is an optimum remedium.

Legislative regimes with compatibility requirements include Greek law which states that, "there must be histocompatibility between the donor and the recipient."<sup>52</sup> Full histocompatibility is required for bone marrow transplantation but it is unclear what level of compatibility is required for other organs. Greece's significant LDT use suggests this provision merely means there must be *some* level of histocompatibility (i.e. not mismatch). Ecuador's law is probably the same in requiring positive histocompatibility results.<sup>53</sup> More liberally, Cypriot law requires donor-recipient immunological compatibility between donor and recipient or at least toleration of the biological materials by the recipient according to scientific criteria.<sup>54</sup> Similarly, Mexican law simply requires organ compatibility to be present between donor and recipient and that the recipient can tolerate the transplant. Since clinically mismatched LDT is the only form of LDT inferior to cadaveric donation<sup>55</sup> the histocompatibility requirements act to ensure LDT is justified as the best clinical option.<sup>56</sup>

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<sup>52</sup>Law No. 1383 of 2 August 1983 On the Removal and Transplantation of Human Tissues and Organs at section 5(b).

<sup>53</sup>Law No. 64 of 26 May 1987 Reforming the Health Code at section 2.

<sup>54</sup>Law No. 97 of 1987 On the Removal and Transplantation of Biological Materials of Human Origin at section 7.

<sup>55</sup>See Chapter 3.4.1.

<sup>56</sup>Thus effectively producing a correspondence between such laws and Belgian law.



#### **4.3.6. Other Requirements.**

Although most jurisdictions leave regulation as to required donor health to clinical guidelines some legislatively limit donations on this basis, usually to protect the donor but sometimes to protect the recipient as in the case of Costa Rican law which states that so called 'high risk' persons can not be donors.<sup>57</sup>

A number of legislative regimes require authorisation of LDT by a body or persons independent of the clinicians caring for the recipient (see chapter 6). The requirement for such authorisation has several functions including ensuring voluntariness and an adequate clinical justification for LDT.

#### **4.3.7. Conclusion.**

Most legislative requirements in this area are very basic but in some cases laws favour cadaveric donation or otherwise significantly restrict LDT. Even a non-restrictive law is ultimately no guarantee of choice for the potential living donor - there is no right to donate and as such the donor will be somewhat beholden to clinical judgement at the local transplant centre or to finding an alternative centre which will undertake the procedure. Some issues are almost universally left as a matter for individual centres and / or national guidelines; e.g. criteria on who is acceptable for transplantation on clinical criteria. Legislative preconditions that may be considered useful are: the requirement that LDT is the optimum remedium in the circumstances of the individual case; *and* the requirement that LDT is undertaken for therapeutic purposes. Other legislative controls are basically superfluous - although health and safety stipulations (e.g. donor health) may be necessary in some circumstances to obtain a consistent national or international approach, ensure high standards and allay public concerns.

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<sup>57</sup>These are defined as; (a) homosexual or bisexual men; (b) female prostitutes; (c) promiscuous men; (d) drug injecting drug dependent persons; (e) persons receiving blood or blood products; and (f) women who have had sexual relations with men belonging to groups (a), (c), (d) and (e). This also applies to anyone with HIV but any person belonging to one of the above groups may be a donor if they are found to not be HIV positive (see Decree No. 17533-S of 8 May 1987 at section 1-4).



## **4.4. Limiting Parameters to Definite and Potential Donor Detriment in LDT.**

### **4.4.1. Introduction.**

The Council of Europe's Draft Bioethics Convention stresses that parties to transplantation should protect the dignity and identity of all human beings, and guarantee everyone respect for their integrity.<sup>58</sup> This philosophy has been one of the factors behind legal limitations on the level of prospective detriment for living donors which include parameters restricting the acceptable level of definite harmful consequences stemming from a procedure *and* restriction of levels of permissible risk involved in undergoing a procedure. They can also be placed in the context of anticipated benefits as is the case within the Council of Europe Resolution (78) 29<sup>59</sup> provision which states that where the removal of substances presents a foreseeable substantial risk to the life or health of the donor a removal may be permitted exceptionally where it is justified by the motivations of the donor, the family relationship with the recipient<sup>60</sup> and the medical requirements of the case. The Draft Convention on Bioethics is more explicit on this point in stating that, "no organ shall be collected if the risk for the donor is disproportionate to the benefit expected for the recipient."<sup>61</sup> The Council of Europe is currently developing a new Protocol on organ transplantation but this is unlikely to comment further on the question of detriment.

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<sup>58</sup>Article 1 of the Draft Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Bioethics Convention and Explanatory Report. Dir/Jur (94)2 directorate of Legal Affairs, Strasbourg, July 1994. Note that this draft was developed into a 'Convention on Human Right and Biomedicine,' adopted by the Committee of Ministers on 19 November 1996 (Dir/Jur (96) 14) which has recently been published.

<sup>59</sup>Adopted by the Committee of the Council of Europe, 11 May 1978.

<sup>60</sup>Article 5. Case law relating to capacity and LDT has emphasised the question of close relationship and it would just as likely be a factor here - since the public interest is likely to be determined not just by what risks are being taken but by the likely value of taking them.

<sup>61</sup>For further discussion of the Convention see C.Byk, Living Organ Donation: European Perspectives in D.Price and H.Akveld, Living Organ Donation in the Nineties: European Medico-Legal Perspectives, *EUROTOLD*, 1996, 49-57.



Limits to detriment are explicitly laid out within most transplant legislation. There are a few exceptions, such as France,<sup>62</sup> whilst some jurisdictions only partially regulate on this point - for instance Hong Kong's Ordinance and UK law both of which regulate limits for certain forms of donation requiring special authorisation (i.e. respectively donations not defined as between genetic relatives or spouses of 3 or more years standing and those not defined as between genetic relatives<sup>63</sup>). General law has principles which often restrict the detriment a person may endure - including detriment in medical procedures, although there have been no cases of LDT. General law provides not just a useful comparison with but in some cases a clarification of the meaning of provisions within transplant legislation.

Inevitably, limits to detriment raise tensions between the self-determination rights of donors and concerns that procedures can be justified as minimal in their level of maleficence. These concerns stem not just from a perception of the interests of the donor (as perceived by others and in terms of the danger of undue influence) but also the rights of organisers of transplantation and the public to have an efficient, publicly well regarded, system operating within reasonable ethical criteria.

#### **4.4.2. Legislative Limits to Detriment.**

There are a large number of jurisdictions regulating limits to the levels of definite and possible consequences a prospective donor may endure. Some provisions require medical professionals to certify that risks are below a certain level. For instance, Bolivian law states that at least two physicians must certify that removal of the organ will not seriously damage the donor's health or chances of survival.<sup>64</sup> Under Russian

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<sup>62</sup>Old French laws and the recent 1994 law have no provision on this point (*IDHL*, 1994, 45(4), 473-482 - The law was also presented in it's draft form as the Bill On Use of Human Parts and Assisted Procreation, Bull. Med. Eth./March 1993).

<sup>63</sup>Ordinance No. 16 of 1995 To Prohibit Commercial Dealings in Human Organs Intended For Transplanting, to Restrict the Transplanting of Organs Between Persons Who Are Not Genetically Related, to Regulate the Importing of Human Organs Intended for Transplanting and For Supplementary Purposes Connected With These Matters (The Human Organ Transplants Ordinance) section 5(4)c(ii).

<sup>64</sup>Regulations On the Use of Organs and Tissues 15 March 1982 at section 3(b).



Federation law a living donor may only donate organs or tissue where, according to the findings of a committee of medical specialists, his health will suffer no significant damage.<sup>65</sup> In Greek law there must not, in the opinion of the responsible physicians in the treatment unit where the removal is to be performed, be "any manifest serious risk to the life or health of the donor."<sup>66</sup> Poland,<sup>67</sup> Hong Kong<sup>68</sup> and Canada (model law)<sup>69</sup> also have provisions in this area.

#### **4.4.2.1. Legislation Allowing LDT's That Do Not Jeopardise the Donors Life.**

Romania,<sup>70</sup> Algeria,<sup>71</sup> and Turkey<sup>72</sup> have provisions allowing donation where it does not jeopardise the donors life. In interpretation of these and other provisions referring to life, *de minimus* jeopardy to life would have to be excluded since all organ donation involves a fractional risk of death. Similarly, laws referring to a reasonably foreseeable risk of death<sup>73</sup> must be interpreted as not referring to reasonably foreseeable *de minimus* risk of death.

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<sup>65</sup>Law of 22 December 1992 at section 1.

<sup>66</sup>Law No. 1383 of 2 August 1983 at section 5(c).

<sup>67</sup>Requires that a medical check-up prior to donation ascertains that the risk does not surpass the permissible anticipated limits for such medical operations and does not seriously in an adverse manner the health condition of a donor. Law of 26 October 1995 at Article 9(1) point 4.

<sup>68</sup>Proposed distant genetically related and emotionally related living donations (apart from spouses of 3 years standing) must seek validation from the Board set up under the law. The Board will simply note the risk involved in the procedure at issue as one of the factors bearing on it's determination. Ordinance No. 16 of 1995 To Prohibit Commercial Dealings in Human Organs Intended For Transplanting, to Restrict the Transplanting of Organs Between Persons Who Are Not Genetically Related, to Regulate the Importing of Human Organs Intended for Transplanting and For Supplementary Purposes Connected With These Matters (The Human Organ Transplants Ordinance) section 5(4)c(ii).

<sup>69</sup>Imposes no restrictions for regenerative material but non-regenerative material must be transplanted only in after an independent assessment which will take into account whether the removal will create a substantial health or other risk to the donor. The Uniform Human Tissue Donation Act 1990 at section 7(6).

<sup>70</sup>Presently Article 4(1) of the 1996 Law regarding The Harvesting and The Transplantation of Human Tissues and Organs. Formerly in the Law of July 1978 at section 132

<sup>71</sup>States that the removal of organs or tissues must not endanger the life of the donor (Law No. 85-05 of 16 February 1985 On Health Protection and Promotion at section 162).

<sup>72</sup>Law No. 2238 of 29 May 1979 On the Removal, Storage, Transfer and Grafting of Organs and Tissues at section 8.

<sup>73</sup>Such as Finland (Law No. 355 of 26 April 1985 at section 3).



Another problem is that jurisdictions which are limited to excluding donations that jeopardise life or present a foreseeable risk of death on the face of it are allowing some ethically unacceptable form of donation - such as donation of one or two cornea. Of course, in practice such donations would be outside the limits of acceptable detriment under general principles of law (unless donation was incidental to a removal which was therapeutically necessary for the donor).<sup>74</sup>

#### **4.4.2.2. Legislation Allowing LDT's that Do Not Present a Serious Risk to Donor Health.**

Many laws in this area give rise to legal uncertainty and require considerable interpretation. Spain's law requires that, "the organ concerned must be one whose removal is compatible with the donor's survival and does not seriously diminish his functional capacities."<sup>75</sup> The word "functional" would seem to imply physical functioning but also the ability to work, maintain relationships, etc. Commenting on these restrictions Casabona states that,

"single vital organs may not be removed nor may single remaining organs from pairs...Limbs are also excluded as are any parts of the body the removal of which would involve diminished bodily functions. The removal of paired or double organs is permissible when the remaining organ can act as a functional substitute. The same is true of regenerable tissue (blood, medulla, bones, cartilage, etc.). It is therefore necessary to carry out a full medical examination of the donor so as to determine whether or not his / her current health would result in his / her being seriously affected by the removal of the organ. If the donor's physical and mental health is good enough for the removal to go ahead, a medical practitioner other than those who will perform the operation must make a statement to that effect."<sup>76</sup>

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<sup>74</sup>3 cornea and 26 hearts were live donated in 1991 in the UK on this basis (*UKTSSA 1991 Annual Report*).

<sup>75</sup>Crown Decree No.426 of 22 February 1980 at section 2(b). The law also states the obvious that the donor must be "(i)n a state of health compatible with the removal procedure." section 2(a) *ibid*.

<sup>76</sup>Casabona, *The Living Donor in Spanish Law*, EUROOLD materials.



Under general Spanish law intrusions on bodily integrity are illegal but this transplant law implicitly makes living donation an exception to this law.<sup>77</sup> A reform of the general law in 1983 explicitly recognises living donation as an exception.<sup>78</sup>

Norway's law states that, "(t)he operation may be performed only if no direct danger to the donor's life or health results therefrom"<sup>79</sup> This would make living kidney donation legal but leave the legal status of living liver donation uncertain. Denmark's law states that, "the intervention may only be performed if, taking into account it's nature and the state of health of the person giving consent, it may be undertaken without any immediate danger to that person."<sup>80</sup> This provision would need broad interpretation so as to exclude *de minimus* quantities of immediate danger present in all donations, while Norway's provision would need to exclude *de minimus* quantities of direct danger.

The former GDR law (in force in the 5 new Landers of Unified Germany)<sup>81</sup> requires that *no* damage to the donor's health must be anticipated;<sup>82</sup> unless this law is interpreted broadly LDT will be excluded because some damage is inevitable and there is a small risk of major damage. Paraguay's law also needs to incorporate *de minimus* as a qualification to the provision that the donation must not adversely affect the donor's ability to live.<sup>83</sup> Slovakia's law prohibits donations which it is anticipated will seriously jeopardise the donor's state of health.<sup>84</sup> Some of the newer, more risky and damaging forms of living donation might be excluded under this provision - in particular pancreas living donation. Cypriot law states that there must be *no* serious and manifest risk to the life or health of the donor, other than that resulting from the removal itself.<sup>85</sup> Clearly

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<sup>77</sup>Casabona, The Living Donor in Spanish Law.

<sup>78</sup>Ibid.

<sup>79</sup>Law No. 6 of 1973 On Transplantation, Hospital Autopsies, Donations of Bodies etc. at section 1.

<sup>80</sup>Section 13(4) Law No. 402 of 13 June 1990 On the Examination of Cadavers, Autopsies and Transplantation etc.

<sup>81</sup>Applying in the 5 Landers of Germany that were formerly East Germany.

<sup>82</sup>Section 6 of The Ordinance of 4 July 1975. All living donation necessarily involves some damage!

<sup>83</sup>Law No. 836180 of 15 December 1980 Promulgating the Health Code.

<sup>84</sup>Law of 24 August 1994 at section 46(2).

<sup>85</sup>Section 7 of Law No. 97 of 1987.



all forms of LDT have serious and manifest risks to donor health - it is only that the more serious risks are very unlikely to actualise, except in more marginal cases and forms of organ LDT.

Fortunately, a few pieces of legislation have relatively simple provision in this area. Portugal's law is clearly framed, stating that donations shall not be permitted if, "there is a strong probability of serious and permanent impairment of the physical integrity and health of the donor."<sup>86</sup>

Other jurisdictions regulating on this point include Finland,<sup>87</sup> Lebanon,<sup>88</sup> Slovenia,<sup>89</sup> Russian Federation,<sup>90</sup> Hungary,<sup>91</sup> Argentina.<sup>92</sup>

#### **4.4.2.4. Laws Placing Restrictions by Reference to Particular Types of Organs.**

A significant number of laws, mostly outside western Europe indirectly place a degree of restriction on donor detriment via restricting the range of organs that are donatable.

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<sup>86</sup>Law No. 12 of 22 April 1993 On the Removal and Transplantation of Human Organs and Tissues at section 6(4). Under ordinary circumstances LDT kidney donation would be legally acceptable in Portugal because the risk of serious and permanent impairment of the physical integrity and health of the donor is minimal. The outer limits of consent could potentially be transgressed if there was some special risk due to the condition of the donor or a different form of organ being transplanted.

<sup>87</sup>The law states that, "(t)he intervention shall not entail a serious risk to, or harm the health of, the donor...the transplant (must) not involve any reasonably foreseeable risk of death or total permanent incapacity of the donor" (Law No. 355 of 26 April 1985 at section 3).

<sup>88</sup>Tissues or organs can't be removed from a person whose, "state of health precludes such removal or if there is a risk or serious danger to the health of the donor." Decree No. 109 of 16 September 1983 On the Removal of Human Tissues and Organs for Therapeutic and Scientific Purposes at section 1.

<sup>89</sup>Has the very basic requirement that the donation must be a reasonable risk for the donor and recipient and have a strong possibility of success. 1996 law at Article 2.

<sup>90</sup>According to team of medical specialists donor's health must suffer no significant damage (Law of 22 December 1992 at section 1).

<sup>91</sup>Three physicians from the medical establishment not involved in the removal and transplantation procedures must determine that the donor will not suffer irremediable injury (Ordinance No. 18 of 4 November 1972 at section 1(3)).

<sup>92</sup>LDT is only considered if it would not seriously harm the health of the donor. Law No. 24193 of 24 March 1993 On The Transplantation of Organs and Anatomical Materials at section 14. The old (repealed) law states that only one of two paired organs may be removed and only anatomical materials whose removal does not entail any reasonably foreseeable risk that the donor will die or be completely or permanently disabled (Law No. 21541 of 21 March 1977 On the Removal and Transplantation of Organs and Anatomical Materials at section 12).



Provisions in this area are sometimes *de minimus* in the sense that the restriction applies to organs that if donated would result in severe damage or death to the donor. For instance, Tunisian law prohibits only the removal of the entirety of a vital organ of a living person,<sup>93</sup> Syrian Arab Republic law has a similar provision while Russian Federation law merely restricts donation to, "(a) paired organ, a part of an organ, or a tissue whose absence does not entail any irreversible damage to health may be removed from a living donor."<sup>94</sup>

Some laws have clearly become outmoded by the fast pace of medical science. Colombian<sup>95</sup> and Hungarian laws<sup>96</sup> only permit permit donation of organs where they are one of a pair organs. Both laws were developed before LDT's of parts of single organs such as liver and lung were occurring - the laws effectively prohibit such donation.

Romania has a novel provision stating that the donor cannot donate vital organs or reproductive organs contrary to human nature - a provision which bans artificial reproductive technologies.<sup>97</sup> Harvesting of unique organs such as heart, liver, pancreas etc. can only be performed from brain-dead persons; this apparently precludes a clinically indicated domino heart procedure.<sup>98</sup> These prerequisites are general to all transplants with no added requirements for a LDT.

Other jurisdictions with regulation on this point include Peru,<sup>99</sup> Argentina,<sup>100</sup> Belarus draft law,<sup>101</sup> Bolivia,<sup>102</sup> Ecuador,<sup>103</sup> Kuwait<sup>104</sup> and Panama.<sup>105</sup>

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<sup>93</sup>Vital organ in this context meaning one whose withdrawal would inevitably entail the death of the person from whom it was removed. The law states that the organ must not be one that is essential to life even if the donor has given consent (Law No. 91-22 of 25 March 1991 at section 4).

<sup>94</sup>Law of 22 December 1992 at section 12.

<sup>95</sup>Law No. 73 of 20 December 1988 at section 3(a). Colombian provision adds that "the donation of one of the paired organs shall only be permitted if it's removal does not entail serious prejudice or mutilation for the living donor and it's purpose is a transplantation that is indispensable from the therapeutic standpoint" (Decree No. 1172 of 6 June 1989 at section 24). "At the time of organ removal, the organ donor must not be suffering from any disease liable to be aggravated by the withdrawal of the donated organ and if the donor is a woman, she must not be pregnant" (ibid at section 35f).

<sup>96</sup>Ordinance No. 18 of 4 November 1972 at section 1(3).

<sup>97</sup>Article 8(2) ibid.

<sup>98</sup>Article 9(3) ibid.

<sup>99</sup>Supreme Decree No. 014-88-SA of 19 May 1988 at section 14 - see *IDHL*, 1994, 45(1), 36-7 at p37.



#### 4.4.2.5. Regenerative Non-Regenerative Distinctions and Donor Detriment.

As a variation of the above, a few legislative regimes restrict donation of non-regenerative body materials (i.e. organs with the exception of liver segment) which indirectly places some limits to the degree of donor detriment. The most potent example is Slovenian law under which tissues must, as a rule, be reviving to be donated.<sup>106</sup> Liver segment and single kidney donation are acceptable for the sake of transplantation into a person who is "genetically or family linked" to the donor if it is not possible to get a cadaver within a reasonable time and use of LDT "assures much better possibilities of medical treatment"<sup>107</sup> and ethical committee approval is also given.<sup>108</sup> Through this approach, Slovenian law prohibits several viable forms of organ LDT (including lung, domino-heart, small bowel, pancreas and cornea).<sup>109</sup> Other regimes with legislative provision on this issue include Peru<sup>110</sup> and Bolivia.<sup>111</sup>

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<sup>100</sup>Law creates regulations which determine the list of organs which are acceptable for living donation (Law No. 24193 of 24 March 1993 On The Transplantation of Organs and Anatomical Materials at section 15). Special provisions are provided for bone marrow.

<sup>101</sup>Allows donation of, "a paired organ, part of an organ, or a tissue whose absence does not entail irreversible damage to health may be withdrawn from a living donor for transplantation purposes" (section 6). This section also contains provisions relating to the safety of recipients.

<sup>102</sup>Allows donation of organs that are double or multiple, so that removal of one of them will not seriously damage the donor's health, and organs and tissues that by their nature are capable of regeneration or are replaceable. Risks must be certified as within certain limits (Regulations On the Use of Organs and Tissues 15 March 1982 at section 2 and 3(b)).

<sup>103</sup>Provides that the transplant must be of a duplicate organ, or involves anatomical materials or tissues from organs whose removal does not involve any reasonable foreseeable risk of death or total or permanent incapacity of the donor and that the donor has a favourable medical opinion from a physician concerning his state of health and from a psychologist concerning the probable consequences of the transplant for his personality. Transplantation is prohibited if it involves a threat to the life of the donor or of a significant deterioration of his health (Law No. 64 of 26 May 1987 Reforming the Health Code at section 2).

<sup>104</sup>States that an organ can't be removed even with consent; "if the removal is liable to bring about the death of the donor or prevent him carrying out his activities (Decree-Law No. 55 of 20 December at section 3).

<sup>105</sup>Prohibits donations when, "it may reasonably be presumed that such removal may entail the death or permanent and total invalidity of the donor." Law No. 10 of 11 July 1983 at section 6.

<sup>106</sup>1996 law Article 8.

<sup>107</sup>It is unclear what the ambit of family and genetic links is under the law.

<sup>108</sup>Article 8 *ibid*.

<sup>109</sup>unless the stipulation that *as a rule* body material must be reviving is not just allowing liver segment and kidney to be exceptions but also other organ in exceptional circumstances

<sup>110</sup>Provides that living donation can only be carried out with regenerable or restorable tissues or with paired organs such that the donor's life is not endangered. Supreme Decree No. 014-88-SA of 19 May 1988 at section 14 - see *IDHL*, 1994, 45(1), 36-7 at p37.



#### 4.4.2.6. Conclusions.

There are widely varying legislative approaches to limiting detriment that the donor can endure. The differences are more about the failure of jurisdictions to harmonize according to rational principles than any legitimate expression of societal difference. Provisions are also often vague in certain areas, in particular specification of what levels of consequences and risks of donation are acceptable is often so inexact as to be worthless. Practitioners are used to assessing questions of risk in medical procedures but living donation is exceptional in that it is a 'rescuing volunteer' rather than a patient at issue. Clear legislative provision, rather than restricting practitioners, would actually serve to encourage them to undertake living donation where appropriate in the knowledge that they are operating within a clear and legitimating framework.

Risks and consequences can be of all types and degrees. What really matters is that the overall package of detriment is within reasonable limits. To avoid professional uncertainty leading to professional inaction an authority set-up by legislation could be referred to by practitioners in more marginal cases. Legislation needs to include limits to donor detriment in terms of level (e.g. minimal) of definite consequences of donation and level of possibility (e.g. minimal) that more serious harms will materialise. Legislation can specify what organs are permissibly donated; however, it must be borne in mind that medical advancements can make provisions outdated. In light of this it seems better to address this issue in a more flexible manner (e.g. delegated to an authority set-up by the legislation itself). A final point may be made that some jurisdictions limit the level of detriment that a minor or adult incompetent may endure by limiting the donatable range of body materials. The details of such an approach are considered in chapter 7.

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<sup>111</sup>Allows donation of organs and tissues that by their nature are capable of regeneration or are replaceable in addition to organs that are double or multiple, so that removal of one of them will not seriously damage the donor's health. Risks of all LDT must be certified as within certain limits. Regulations On the Use of Organs and Tissues 15 March 1982 at section 2 and 3(b).



#### **4.4.3. Limits to Detriment Under General Principles of Law: A Case Study of English law.**

The cases most relevant to the question of limits to detriment in organ donation is the Canadian one of Urbanski v Patel [1978] 84 DLR 3d 650, which would probably be followed in all common law countries. In Urbanski it was stated, obiter dicta, that a person can only donate one of a pair of vital organs. At first glance it would seem bizarre that anyone would want to do more than this of their own volition (i.e. without coercion or undue influence). However, one of the donors I interviewed subsequently offered to donate a second kidney.<sup>112</sup> This offer was the subject of a television documentary entitled 'The Decision: Whose Kidney Is It Anyway?'<sup>113</sup> The potential donor was the father of two son's who had a kidney disease and had already given an organ to one of them and wanted to give away his second to his other son. The main element of his reasoning was that he was old and retired and could live on dialysis for a while his son needed a transplant very much and it may enable him to live a fruitful life. This potential donation was being seriously discussed by a London hospital. This indicates that a person can have a rational reason for wanting to donate an organ which is essential to good health. However legally they would almost certainly be shackled from doing so; besides the Urbanski case there is the well established principle in common and civil law countries that a person cannot consent to being killed, self mutilated or seriously injured.<sup>114</sup> These principles would probably apply in any jurisdiction where there is no legislative provision for the question of limits to detriment. An example would be the UK, where the English case of R v Donovan [1934] 2 KB 498 suggested that a purported consent to a procedure causing death, mutilation or serious injury would be null and void with the surgeon committing the criminal offences of intentionally causing grievous bodily harm with intent to do so<sup>115</sup> and maim.<sup>116</sup> Clearly, the whole removal of an essential organ (e.g. cornea, an only kidney, heart) would be unlawful

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<sup>112</sup>English interviews with living donors and recipients are discussed in chapter 8.

<sup>113</sup>Tuesday 20 February 1996 at 9pm on Channel 4.

<sup>114</sup>D.Gieson, International Medical Malpractice Law, *Martinus Nijhoff*, 1988, 609.

<sup>115</sup>Under section 18 of The Offences Against The Person Act 1861

<sup>116</sup>See R v Wright [1603] 1 Co. Inst. 127.



(unless incidental to a therapeutic removal).<sup>117</sup> Additionally, more novel forms of living donation carrying uncertain and potentially higher risks / more serious harms and in those situations where the prospective donor has a precondition leading risks to be considerably higher.<sup>118</sup>

The question arises: would judges go further and restrict detriment proportionate to benefits? At this point the ethical conflict between autonomy and beneficence is amplified. Preventing donation where it does not have a good benefit to detriment ratio could be highly paternalistic. The prospective competent donor must be viewed as legitimately possessing the right to take into account what factors to take into account and how to assess these, including the likely benefits to the prospective recipient. Consequently Skegg has suggested that,

"a court is unlikely to inquire closely into whether there are good reasons for a particular intervention. There is no danger of a court attempting to decide whether there are good reasons for removing a kidney from a living donor, instead of keeping the patient on dialysis in the hope that a suitable cadaver kidney would become available."<sup>119</sup>

Nethertheless, while the competent donor has every right to make his or own assessment, the organisers and regulators of transplantation have their own legitimate right to prevent those LDT's which are clearly against public interest. The public has a right for it's resources to be used efficiently and ethically, transplant organisers have a right to decline to engage in procedures they regard as unethical or inefficient and both organisers and public have a legitimate interest in protecting the reputation of transplantation as something carried out under responsible conditions. Clearly, while the law must allow participants some leeway in determining what is a beneficent procedure it must not allow so much leeway as to denigrate the responsible practice of transplantation. This matter

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<sup>117</sup>See K.Norrie, Human Tissue Transplants: Legal Liability in Different Jurisdictions, *I.C.L.Q.*, 1985, 42, 442 at 447 who suggests that cornea donation simply for the benefit of the recipient is unlawful.

<sup>118</sup>The position appears similar to that developed in many of the earlier discussed statutory regimes.

<sup>119</sup>Law, Ethics and Medicine: Studies in Medical Law, *Clarendon Press*, 1988.



is really a role for legislation, although common law inevitably does take into account anticipated benefits when determining what activities are too detrimental to be legal (see 4.3).

Carl Elliott's leading article, 'Doing Harm: Living Organ Donors, Clinical Research and *The Tenth Man*,<sup>120</sup> confirms the ethics of this approach to risk taking. On the one hand it could be argued that the donor has a right to take high risks but on the other we are faced with Elliot's question: "What would we think of a person who would take advantage of a donor's willingness to take life-threatening risks?"<sup>121</sup>

Elliot poses the further point that when someone chooses to risk themselves they also risk harming others.<sup>122</sup> He rightly suggests that these effects should be taken into account.<sup>123</sup> Elliot also suggests a common sense principle that "any system of practices in which people are likely to be harmed should be set up in ways that minimize this possibility." This includes not having incentives to engage in practices like organ donation encouraging the risk of donating, "for example it would be better to have a system of living organ transplantation in which nobody is able to make a financial profit from the procedure."<sup>124</sup>

#### **4.4.4: Conclusions on limits to detriment.**

Statutory provisions usually require *justifications* for taking the risks and enduring the consequences of living donation. *Firstly*, the justification is often seen in terms of the *clinical conditions* present. This could for example be that living donor transplant is the best available clinical option, or that the recipient is in danger of losing life. *Secondly*, LDT is sometimes seen as necessitating a *special relationship between the*

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<sup>120</sup> *J Med Eth*, 1995, 21, 91-96.

<sup>121</sup> Doing Harm: Living Organ Donors, Clinical Research and *The Tenth Man*, *J Med Eth*, 1995, 21, 91-96 at 94.

<sup>122</sup> *Ibid* at p96.

<sup>123</sup> *Ibid* at p96.

<sup>124</sup> *Ibid*.



*donor and recipient* as a justification for risk taking. Medical practitioners are usually responsible for ensuring justifications are met; failure to meet them may constitute a statutory offence.<sup>125</sup> The role of common law is more limited in placing limits to detriment without being likely to enquire in a more detailed way as to the justifications for particular donations. Jurisdictions based on common law principles for the area of detriment are likely to offer more leeway to practitioners. From the practitioner perspective this isn't necessarily advantageous if it leaves more responsibility to the individual transplant centre or practitioner to assess on a case by case basis, and through centre policy, which transplants reflect a fair detriment to benefit ratio. This is very much an area that might be best suited to the use of national codes of practice which can be adapted more easily than legislation to reflect changing transplantation practice and technology. Alternatively/additionally an authority set up under law could be given responsibility for authorisation of LDT's in certain situations.

#### **4.5. Procedural Requirements Relating to the Formation of a Legally Valid Consent.**

A general rule of medical law is that medical treatments and procedures can be undertaken without procedural formalities. However, within many jurisdictions, living organ donation provides an exception to the rule through transplant legislation requiring certain procedural formalities to be observed. Most legislative regimes prescribe procedural requirements in the the formation of a valid consent for the donor and in some cases for the recipient.<sup>126</sup> Some statutory regimes only partially deal with questions of procedure in consent. For instance UK law requires procedural requirements to be met

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<sup>125</sup>Such failure tends to be statutorily defined as invalidating the consent. Of course questions of justification can be a part of general principles of law and failure to satisfy requirements can invalidate consent here.

<sup>126</sup>The legislation of Cuba (Decree No. 139 of 4 February 1988 at section 80) and that of Ecuador (Law No. 64 of 26 May 1987 Reforming the Health Code) do not regulate on points of substance and procedure in consent. Nor do the legislative regimes of Austria and Malaysia simply because they are limited in ambit to cadaveric donation. Several regimes are limited in the ambit of organs they cover or other ways. See, for example, the legislation of Italy (various), Columbia (Decree No. 1172 of 6 June 1989), Vietnam (Law of 1989 On the Protection of Public Health at section 30), Kuwait (Decree Law No. 55 of 20 December 1987 On Organ Transplantation).



for the authorisation of non-genetically related donation only.<sup>127</sup> A similar approach is taken in the laws of Hong Kong<sup>128</sup> and India.<sup>129</sup> Argentinean law<sup>130</sup> and the Canadian model law<sup>131</sup> appear to impose no procedural requirements. The special position of the donor and the recipient arguably justifies special legislative attention. Donors are volunteers enduring risks and harmful consequences<sup>132</sup> and some forms of donation are experimental, with uncertain risks and benefits. These factors intimate the need for procedural protection as does the real possibility of commercial organ dealings and / or ‘foul play.’ Recipients have, as already examined, a peculiar interdependence with the donor making accepting a living persons organ unlike any other kind of treatment and worth particular procedural protection.

#### **4.5.1: Written Formalities.**

The statutory provisions of the following countries require that donor consent to LDT be given in writing as detailed in Figure 1.

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<sup>127</sup>See HOTA 1989 section 2(3) - discussed at section 4

<sup>128</sup>Ordinance No 16 of 1995.

<sup>129</sup>Act No. 42 of 1994, *IDHL*, 1995, 46(1), 34-38.

<sup>130</sup>Law No. 24193 of 24 March 1993 repealing Law No. 21541 of 21 March 1977 On the Removal and Transplantation of Organs and Anatomical Materials which stated at section 11 that the decisions of the donor and recipient would be made according to regulations.

<sup>131</sup>Uniform Human Tissue Donation Act 1990.

<sup>132</sup>Unless donation is merely incidental to a medically necessary removal.



**Figure 1: Jurisdictions Statutorily Requiring Consent to be in Writing.**

Algeria,<sup>133</sup> Australian state laws of Northern Territory,<sup>134</sup> Queensland,<sup>135</sup> South Australia,<sup>136</sup> Tasmania<sup>137</sup> and Western Australia,<sup>138</sup> Belgium,<sup>139</sup> Costa Rica,<sup>140</sup> Finland,<sup>141</sup> the 5 former GDR Landers of Germany,<sup>142</sup> Lebanon,<sup>143</sup> Mexico,<sup>144</sup> Panama,<sup>145</sup> Poland,<sup>146</sup> Spain,<sup>147</sup> Slovenia,<sup>148</sup> Slovakia,<sup>149</sup> Denmark,<sup>150</sup> Sweden,<sup>151</sup> Norway,<sup>152</sup> Greece,<sup>153</sup> Cyprus<sup>154</sup> (usually),<sup>155</sup> Romania,<sup>156</sup> Bulgaria,<sup>157</sup> Poland,<sup>158</sup> Russian Federation,<sup>159</sup> South Africa,<sup>160</sup> Sri Lanka,<sup>161</sup> Syrian Arab Republic,<sup>162</sup> The Philippines,<sup>163</sup> The Netherlands,<sup>164</sup> Turkey,<sup>165</sup> Venezuela,<sup>166</sup> Zimbabwe,<sup>167</sup> Hungary which requires that the donor make a declaration signifying his consent to the removal in a written document drawn up by a notary and kept in the clinical file of the donor<sup>168</sup> and Portugal which requires consent to be given in the presence of a physician (who is not a member of the transplant team) designated by the clinical director of the establishment in which the removal takes place.<sup>169</sup>

<sup>133</sup>No 85-05 of 16 February 1985 On Health Protection and Promotion at section 162.

<sup>134</sup>No. 121 of 1979 The Human Tissue Transplant Act at section 8.

<sup>135</sup>The Transplantation and Anatomy Act 1979-1984 at section 10.

<sup>136</sup>The Transplantation and Anatomy Act 1983 section 9(1).

<sup>137</sup>The Human Tissue Act 1985 at section 7.

<sup>138</sup>Act No. 116 of 1982 To Make Provision for and in Relation to the Removal of Human Tissues for Transplantation, for Post-Mortem Examinations, for the Repeal of the Tissue Grafting and Processing Act etc... at section 8.

<sup>139</sup>Law of 13 June 1986 On The Removal and Transplantation of Human Organs section 8(2). See additional procedural requirements under the Crown Order of 30 October 1986 regulating the method of expressing Consent to the Removal of Organs and Tissues From Living Persons.

<sup>140</sup>Law No. 5560 of 20 August 1974 On Human Transplants at section 15.

<sup>141</sup>Law No. 355 of 26 April 1985 On the Removal of Human Organs and Tissues for Medical Purposes at section 2.

<sup>142</sup>GDR law is still in force in the five landers of unified Germany that were formerly East Germany.

<sup>143</sup>Decree No. 109 of 16 September 1983 On the Removal of Human Tissues and Organs for Therapeutic Purposes at section 1(3). The recipient must also have given written consent - section 3.

<sup>144</sup>Federal Regulations of 16 August 1976 On the Use of Human Organs, Tissues and Cadavers at section 24.

<sup>145</sup>Law No. 10 of 11 July 1983 Regulating the Transplantation of Organs and Anatomical Parts and Laying Down Other Provisions at section 21.

<sup>146</sup>Article 9(1) at point 7 of The Law of October 26, 1995, Regulating The Removal and Transplantation of Human Cells, Tissues and Organs.

<sup>147</sup>Law No. 30 of 27 October 1979 On the Removal and Transplantation of Organs at section 4(c)

<sup>148</sup>The Law of the Transplantation of Human Body Parts For The Sake of Medical Treatment 1996 at Article 10. The recipient must also express consent in written form (Article 6).

<sup>149</sup>Law No. 277 of 24 August 1994 at section 46(1).

<sup>150</sup>Section 13(1) of Law No. 402 of 13 June 1990 On the Examination of Cadavers, Autopsies and Transplantation, etc.

<sup>151</sup>The Transplantation Law (No. 190) of 15 May 1975 at section 4.

<sup>152</sup>Law No. 6 of 9 February 1973 On Transplantation, Hospital Autopsies, Donations of Bodies etc. at section 1.

<sup>153</sup>Law No. 1383 of 2 August 1983 On the Removal and Transplantation of Human Tissues and Organs at section 5(d).



## **4.5.2. Additional Procedural Requirements.**

### **4.5.2.1. Information Giving**

In practice the donor may receive information from a variety of sources but several legislative regimes identify a person responsible for information giving.<sup>170</sup> Usually the legislation does not apply to recipients. Sometimes information must be given by the person expected to undertake the removal (e.g. under the legislative regimes of Greece,<sup>171</sup> Turkey,<sup>172</sup> Hungary,<sup>173</sup> Belgium<sup>174</sup> and Panama<sup>175</sup>). This aids proficient information

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<sup>154</sup>Section 4 of Law No.97 of 1987 On the Removal and Transplantation of Biological Materials of Human Origin at section 7(2).

<sup>155</sup>Alternatively consent can be given orally in the presence of witnesses with a declaration being recorded in a dedicated register) see *ibid* at section 7(2).

<sup>156</sup>Article 4(1) of the Law Regarding The Harvesting and The Transplantation of Human Tissues and Organs 1996 replacing an identical requirement in the Law of July 1978 on Satequardy of the Health of the Population at section 132.

<sup>157</sup>Removal of Human Organs for Therapeutic Purposes. Ordinance No.15 of the Minister of Public Health On the Transplantation of Human Organs at section 2 (April 1976 No.35).

<sup>158</sup>Law of October 26, 1995 Regulating The Removal and Transplantation of Human Cells, Tissues and Organs at Article 9(1) point 7.

<sup>159</sup>Law of 22 December 1992 of the Russian Federation on the Transplantation of Human Organs and / or Tissues.

<sup>160</sup>Act No. 65 of 1983 at section 18.

<sup>161</sup>The Transplantation of Human Tissues Act No. 48 of 1987 at section 7(1).

<sup>162</sup>Law No. 31 of 23 August 1972 On the Removal and Transplantation of Organs from the Human Body at section 2(3).

<sup>163</sup>Presidential Decree No. 856 of 23 December 1975 Promulgating the Code on Sanitation at section 96(a).

<sup>164</sup>Hans Akveld (Dutch EUROTOLD participant) response to the EUROTOLD legal questionnaire.

<sup>165</sup>Law No. 2238 of 29 May 1979 On the Removal, Storage, Transfer and Grafting of Organs and Tissues.

<sup>166</sup>Law No. 4497 of 19 November 1992 On The Transplantation of Organs and Anatomical Materials in Human Beings at section 12.

<sup>167</sup>Anatomical Donations and Post Mortem Examinations Act No.34 of 1976 at section 12(a).

<sup>168</sup>Ordinance No. 18 of 4 November 1972 of The Minister of Health for the Implementation of the Provisions of Law No. II of 1972 on Health Relating to the Removal and Transplantation of Organs and Tissues at section 2 although this can be an oral declaration in the presence of a notary retained in the clinical file of the donor.

<sup>169</sup>Law No. 12 of 22 April 1993 On the Removal and Transplantation of Human Organs and Tissues at section 8(2).

<sup>170</sup>The laws of several jurisdictions impose no requirements on this point e.g. Argentina, GDR, Slovakia, Slovenia, Bulgaria, Russian Federation, Cyprus.

<sup>171</sup>Law No. 1383 of 2 August 1983 at section 5-6.

<sup>172</sup>Law No. 2238 of 29 May 1979 at section 7.

<sup>173</sup>Ordinance No. 18 of 4 November 1972 at section 2(2).

<sup>174</sup>Law of 13 June 1986 at section 9.

<sup>175</sup>Law No. 10 of 11 July 1983 at section 6.



giving but, theoretically at least, could compromise the neutrality of disclosure (e.g. encourage bias in favour of transplantation). There is also potential for deliberate or unconsciously motivated undue influence. The same problems could arise within another group of legislative regimes (including Denmark,<sup>176</sup> France,<sup>177</sup> Portugal,<sup>178</sup> Norway,<sup>179</sup> Romania<sup>180</sup> and Tunisia<sup>181</sup>) which delegate information giving responsibility to persons who *may* be associated with the recipient and / or transplant procedure such as 'a physician.'<sup>182</sup>

The problems of bias and undue influence etc., can be addressed procedurally by applying a form of the 'separation principle;' creating a process / system for informing and caring for the donor that is separate and independent to that utilised for the recipient. The Spanish,<sup>183</sup> Polish,<sup>184</sup> Hong Kong<sup>185</sup> and Sri Lankan<sup>186</sup> legislative regimes invoke separation to the extent of ensuring the donor's information giver is independent of the team conducting the removal. On the other hand, under these regimes the information giver could still be a nephrologist or nurse who is caring for the recipient. Finnish<sup>187</sup>

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<sup>176</sup>Law No. 402 of 13 June 1990 at section 13(3) simply states that it must be a physician who informs.

<sup>177</sup>The physician in charge of the hospital department in which the organ is to be removed (or another physician to whom he has delegated the task employed by the same hospital) is responsible. Decree No. 78-501 of 31 March 1978 at section 1. The recent law adds nothing on this point.

<sup>178</sup>Simply says 'the physician' is responsible - it is unclear from the surrounding text whether this may be any physician or has to be the physician responsible for the removal procedure (Law No. 12 of 22 April 1993 at section 7).

<sup>179</sup>Norwegian law simply requires it to be a physician with information on the nature of the operation and its possible consequences (Law No. 6 of 9 February 1973 at section 1).

<sup>180</sup>Romania's old law the chief physician was required to inform the donor. The new law simply requires it to be 'the doctors' and presumably refers to those doctors who are involved in undertaking the proposed nephrectomy (Article 4(2) of 1996 law).

<sup>181</sup>This law requires the chief physician of the hospital department in which the organ is to be removed to give information (Law No. 91-22 of 25 March 1991 at section 7).

<sup>182</sup>See Denmark's law footnote 177.

<sup>183</sup>Crown Decree No. 426 of 22 February 1980 at section 3.

<sup>184</sup>Law of 26 October 1995 at Article 9(1) point 5.

<sup>185</sup>This law imposes a requirement of authorisation that the potential donor and recipient have had the procedure, its risk and the fact that consent may be withdrawn at any time explained to them by a medical practitioner, not being the practitioner who is to remove the organ. This requirement only applies for potential donations *which are not* by a spouse of 3 years standing or a close genetic relative. Ordinance No. 16 of 1995 The Human Organ Transplant Ordinance at section 5(4)c.

<sup>186</sup>This law requires a medical consultant, other than a medical consultant attached to the transplant team, to give information (The Transplantation of Human Tissues Act, No. 48 of 1987 at sections 7 and 8).

<sup>187</sup>Law No. 355 of 26 April 1985 at section 3 states that the information giver must be a physician who is not caring for the recipient.



and Swedish<sup>188</sup> legislative regimes address this problem by requiring that the donor's information giver should be separate from the person who is caring for the recipient. How far laws should go to uphold the 'separation' principle is a difficult question. A theme developed further in chapter 6 is that the voluntariness of a donor's consent is critical, especially given that the essential justification for donation is that the donor is a volunteer. Another theme developed in chapter 6 is that there is solid empirical evidence and psychological theorising to suggest that at least a significant minority of donations are subject to pressure and undue influence. Taking these matters into account, it may be important that legislative regimes uphold the principle of separation at least in the shape of the donor's information giver being independent of the care of the recipient.

#### **4.5.2.2. Written Consent Before Specified Persons or Authorities.**

Several countries require consent to be evidenced before specific person(s). There are 3 distinct approaches:

- *Firstly* the routine matter of consent before a medical authority (such as a physician independent of the transplant team) expressly required under some laws (e.g. GDR,<sup>189</sup> Portugal<sup>190</sup> and Polish law<sup>191</sup>).
- *Secondly* consent before a legal authority (e.g. Greece,<sup>192</sup> Spain<sup>193</sup> and France<sup>194</sup>).

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<sup>188</sup>The responsibility is with the chief physician or the assistant chief physician at the hospital (not being the physician in charge of the care of the recipient patient). Law No. 190 of 15 May 1975 at section 5 read in conjunction with section 3.

<sup>189</sup>This law, applying in the 5 new Landers of unified Germany that were formerly East Germany, states that the donor's consent shall be given to the competent local medical officer in the presence of a representative of the medical team carrying out the removal procedure. A report on the details of the information provided and the donor's declaration of consent shall be drawn up and signed by the local medical officer, the representative of the medical team, and the donor.

<sup>190</sup>The law stipulates that consent must be given in the presence of a physician designated by the clinical director of the establishment in which the removal takes place, not being a physician involved as a member of the transplantation team (Law of 1993 at section 8(2)).

<sup>191</sup>This law merely requires that the written consent be given in front of 'the doctor' - which presumably refers to the doctor undertaking the removal procedure (Law of 26 October 1995 at Article 9(1) point 7).

<sup>192</sup>This law which states that the declaration of willingness to donate must be made in notarial form or on a form on which the police authority has confirmed the authenticity of the signature of the potential donor or orally, the declaration being recorded in a special register kept by the treatment establishment where the



- *Thirdly* the use of additional witnesses (e.g. in Turkey,<sup>195</sup> Venezuela,<sup>196</sup> Algeria,<sup>197</sup> Costa Rica,<sup>198</sup> The Philippines<sup>199</sup> and Mexico<sup>200</sup>). The class of person that can be a witness is not usually expressly restricted although in some cases it must be a notary.<sup>201</sup>

Using extra witnesses and, particularly, requiring consent before a judicial authority have the advantage of helping to ward against impropriety such as coercion. However, requiring consent before a legal authority can be criticised as bureaucratic and discouraging of LDT unless it is necessary within a particular jurisdiction where commercial trade in organs and/or coercion is not uncommon. In consent giving, as with information giving, there is a debate between using the separation principle, which helps to ensure no falsification or other 'foul play' and having consent given to a member of the transplant team, which is practically simpler. Statutory approaches tend to emphasise the separation principle.<sup>202</sup>

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removal procedure is to be performed, in the presence of two witnesses who must both sign the declaration together with the donor (Law No. 1383 of 2 August 1983 at section 5).

<sup>193</sup>This law requires that the written consent of the donor be given in the presence of the magistrate responsible for public records in the locality concerned. The consent document must additionally be signed by the other persons present (Crown Decree No. 426 of 22 February 1980 for the Implementation of Law No. 30 of 27 October 1979 On the Removal and Transplantation of Organs section 4(4)).

<sup>194</sup>The French Decree of 1978 stipulated that the donor's consent in writing must also be signed by a witness whom (s)he has chosen, and if the organ to be removed is non-regenerable, the consent must be given in court (Decree No. 78-501 of 31 March 1978 for the Implementation of the Law of 22 Dec 1976 On the Removal of Organs at section 2) however this has been repealed by the 1994 law (No. 94-654 On the Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation, and Prenatal Diagnosis at Article L-671-3 (*IDHL*, 1994, 45(4), 473-482 at 474). This law states that the donor must express consent before the Presiding Judge of the *tribunal de grande instance* (or the judge designated by him) but does not say that this has to be in written form.

<sup>195</sup>Law which requires minor and legally incompetent donors *only* to draw up a written document giving consent to the removal and sign it in the presence of at least two witnesses or give an oral undertaking in the presence of at least two witnesses and then sign a declaration which is then countersigned by a physician (Law of 1979 at section 6).

<sup>196</sup>Law No. 4497 of 19 November 1992 On The Transplantation of Organs and Anatomical Materials in Human Beings at section 12.

<sup>197</sup>Section 162 of Law No. 85-05 of 16 February 1985.

<sup>198</sup>Law No. 5560 of 20 August 1974 On Human Transplants at section 15.

<sup>199</sup>Decree No. 856 of 23 December 1975 at section 96(e).

<sup>200</sup>Federal Regulations of 16 August 1976 at section 24.

<sup>201</sup>E.g. Bolivia (Regulation On the Use of Organs and Tissues 15 March 1982 at section 3) and Uruguay (Decree No. 660/991 of 4 December 1991 at section 4).

<sup>202</sup>A possible exception being Poland (Law of 26 October 1995).



#### 4.5.2.3. Time Lapse Between Agreement and Removal.

The few jurisdictions that legally specify a time lapse between donor agreement and organ removal usually require 24 hours (e.g. Spain<sup>203</sup> and Australian state laws of Northern Territory,<sup>204</sup> South Australia,<sup>205</sup> Tasmania,<sup>206</sup> Western Australia<sup>207</sup> and Queensland<sup>208</sup>). This legally ensures that the potential donor has a chance to reflect and change his / her mind if donating does not reflect his / her true will. Although most jurisdictions have no explicit time lapse requirement it is common transplant practice for significant time delay between donor agreement and removal of the organ. This is done partly as a practical byproduct of needing to work-up the potential recipient for the transplant.

#### 4.5.2.4. Other Requirements

Occasionally legislation contains form and procedures for the purpose of confirming written consent. For example, Romanian law states that the written consent must be given in the form of Annex Number 1 attached to the Act. This involves the donor signing to say (s)he was informed of the risks, asked for and received no payment and consented without pressure, etc.<sup>209</sup> The role of most additional requirements is to protect the prospective donor's right of self-determination.<sup>210</sup>

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<sup>203</sup>At least 24 hours must elapse between the signing of the consent document before the local magistrate and the removal of the organ. Crown Decree No. 426 of 22 February 1980 for the Implementation of Law No. 30 of 27 October 1979 On the Removal and Transplantation of Organs section 4(4).

<sup>204</sup>No. 121 of 1979 at section 9.

<sup>205</sup>The Transplantation and Anatomy Act 1983 at section 10.

<sup>206</sup>The Human Tissue Act 1985 at section 8(1).

<sup>207</sup>Section 9(1) of Act No. 116 of 1982.

<sup>208</sup>The Transplantation and Anatomy Act 1979-1984 at section 11.

<sup>209</sup>Article 4(1) of the Law of 1996 replacing the provision in Law of July 1978 at section 132.

<sup>210</sup>This is not always so, however. For instance Belgium's additional requirements relate partly to obtaining the consent of others in certain circumstances and hence can actually be viewed as a restriction on the rights of the donor. Belgium's law requires that the written consent be evidenced and signed by a witness who is over the age of majority. In addition to the consent of the donor, consent must also be obtained from the donor's spouse (if married) where (s)he is residing with the donor. Additionally where the donor is aged under 21 years consent must be obtained from the person(s) whose consent to the marriage of a minor is required under the Civil Code. Where the removal may be performed on a person



### **4.5.3. Conclusions on Procedural Requirements.**

The presence of written and other formalities for obtaining donor consent reflect the serious, volunteering and non-directly beneficial nature of donation.<sup>211</sup> Procedural requirements have a role in ensuring voluntariness and in impressing on donors the gravity of the undertaking. 'Procedural requirement packages' vary considerably across legislative regimes world-wide, although there is an almost universal requirement for written consent. Legislative variations are not a cause for concern in their own right. However, the paramount importance of voluntariness warrants a more 'across the legislative board' consideration of the methods by which the voluntariness of donation can be protected through procedural requirements. There is a danger of 'procedural overkill' if requirements are made too onerous; for instance requirements that a magistrate witness consent might conceivably put some donors off. At the same time other requirements that would protect donors could be made standard practice such as time lapse between agreement and removal, independence of the donors information giver from the recipient team and the evidencing of the donors written consent by independent witnesses - perhaps even the signing of a statement to say that the donation accorded to his/her true will.

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under 18 (see above), either the consent of the spouse or the person(s) required to consent to the marriage of the minor is required. Law No. 32 of June 1986 at section 6-7.

<sup>211</sup>One ethical argument, however, is that these factors are irrelevant and what matters is the clear protection of people's right to self-determination in all medical procedures. This might lead to procedural requirements being seen as ethically required for all medical procedures or at least more serious ones.



## **Chapter 5: Disclosure and Informed Decision-Making in Organ Donation and Reception.**

### **5.1. Introduction.**

When a competent person is making a medical decision the role of the practitioner is to convey the different options, a view of their possible and definite consequences and recommendation of which course of action to take. The extent of the practitioners duty to disclose has been the subject of considerable debate but has not yet been examined comprehensively in the specific context of the living organ donor and recipient.

Disclosure pits the rights of the decision-maker against those of medical practitioners. A decision-maker uses information as a tool to enhance the practical value of autonomy; understanding the significant facts and possibilities and their place in the decision-making process makes it more likely that one will make a decision according to one's true will. Whilst the practitioners efforts to disclose and ensure understanding of disclosure will influence how a decision is made, whether or not such a decision accords with the true will of the decision-maker is ultimately also about how (s)he uses information in reaching a decision. In this light, most models of rational decision-making have emphasised a deliberative process involving multiple steps, including:

- canvassing a wide range of alternative courses of action;
- surveying the full range of objectives to be fulfilled;
- carefully weighing whatever is known about the costs and risks of negative and positive consequences flowing from each alternative;
- intensively searching new information relevant to further evaluation of the alternatives;
- correct assimilation and taking into account any new information or expert judgement to which the individual is exposed;
- re-examination of the consequences of all alternatives before making a final choice;



- the making of detailed provisions for the implementation or execution of the chosen course of action, with special attention to contingency plans that might be required if various known risks were to materialise.<sup>1</sup>

This model is a useful best practice guide for people making serious decisions. Whilst even very serious decisions such as living organ donation and reception can be based on a person's true will when taken quickly or without rationalised awareness of all these factors even awareness of some or most can help avoid misconceptions or incorrect evaluations (such as over-expectations of benefits and/or underestimation's of detriment) that could result in a donor or recipient making a decision that did not reflect their true will.

Practitioners cannot be expected to be responsible for ensuring the normative ideal of comprehensively informed decision-making is met. For instance, it would be unreasonable to expect disclosure of every single known detail about the prospective ramifications of a procedure and its alternatives. On the other hand if a practitioner is withholding particular information in order to influence a patient to take a particular course of action the question of 'who's decision is it anyway?' is raised. Can a practitioner in the interests of his/her conception of beneficence (or avoiding maleficence) limit the patients right to know and hence interfere with the patient's autonomy? What level of responsibility is it reasonable to impose on a practitioner to make checks on patient understanding of information? This question is central to the debate because, for instance, if a patient doesn't understand the core factors about a procedure and its alternatives (e.g. main detrimental and beneficial definite and possible consequences) the autonomy of decision-making is undermined.

A practitioners level of responsibilities must also relate to the context including the seriousness, complexity and prospective detriment and benefits of a procedure and its alternatives and the individual characteristics of a decision-maker. Gieson<sup>2</sup> categorises three types of medical procedure; therapeutic treatment, therapeutic experiments and research experiments stating that an amplification of disclosure responsibilities takes place through categories 1-3. The unique position of living organ donors and recipients is illustrated by the application of these 3 categories to LDT.

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<sup>1</sup>I.Janis and L.Mann, *Decision Making: A Psychological Analysis of Conflict, Choice and Commitment*, *The Free Press*, 1977 at 11

<sup>2</sup>Civil Liability of Physicians For New Methods of Treatment and Experimentation: A Comparative Examination, *Med Law Review*, 1995 (Spring), 3, 22-52 at 25.



For the prospective *donor* organ LDT effectively represents a *fourth* category of *non-therapeutic procedure with a therapeutic purpose* that can be subdivided as 'standard' and 'experimental.' The donor has to consider much the same issues as the recipient but in many ways is in a more vulnerable position as a potential 'saviour' or 'rescuer' rather than a person undergoing a procedure for direct benefit. In tort law rescuers have traditionally gained very strong legal protection.<sup>3</sup> In terms of degree a donor is undergoing a procedure worthy of a similar level of practitioner responsibility to disclose as research experiments, at least if the procedure is experimental or is not insignificant in its level of prospective detriment.

For the *recipient* most forms of LDT will be *therapeutic treatment*, whereby (s)he is treated by normal and approved (or orthodox) procedures. However, recipient treatment by new methods and techniques for primarily (though not exclusively) therapeutic purposes would be a therapeutic experiment (also known as therapeutic research or 'innovative therapy'<sup>4</sup>). LDT reception will normally not be a research experiment in respect of the fact that it is done for more than purely scientific purposes. No doubt some recipients will not give ethical issues relating to LDT more than a glancing reflection but they can be seen to have a right to deep and wide-ranging information and to understand that information as a necessary foundation for weighing and balancing-up the fundamental aspects of the choice at hand. Several issues heighten the demand for disclosure including: the placement of the donor (potentially a family member) in jeopardy; questions of the donor's motivation; issues of receiving an 'alien' body part; subtle issues of family dynamics and power and of course the general fact that it is a major treatment decision.

The issue, not hitherto significantly considered in LDT literature, is that donor and recipient have a *special interdependence which amplifies the need for disclosure to both* of them in general. The interdependence of donor and recipient also specifically makes it important that both be given information on the definite and possible consequences and ramifications for the other, as well as his/her self, and the alternative options. Interdependence generates these requirements because a person cannot make a rational decision about whether to donate or receive without being informed of, and sufficiently understanding, the prospective impact on the other as well as his/herself. In addition, having a lower standard of disclosure to the recipient could be considered to impact negatively on the morality of decision making

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<sup>3</sup>Medical Law: Text With Materials, *Butterworths*, 1994, 1138.

<sup>4</sup>*Zimmer v Ringrose* [1981] 28 A.R. 69, (1981), [1981] 4 W.W.R. 75 (C.A.).



as seen in the context of the second and third of Schwartz's three necessary and sufficient conditions for a moral decision:

- an awareness of the consequences of one's decision (meaning a recipient would have to fully aware of all significant aspects of living donation and it's alternatives as they affect both him/her and the donor); *and*
- an ascription of personal responsibility to the self rather than a denial of the responsibility for the consequences (meaning that to help ensure morality of decision-making the recipient should be given disclosure as above, like it or not).<sup>5</sup>

For the purposes of this chapter practitioner responsibilities to donors and recipients are divided into two categories:

- *Firstly*, the substance of information communicated including the types of information to be communicated and the depth of information communicated; *and*
- *Secondly*, effective communication of information and checks to ensure it has been understood.

## **5.2. Disclosure and Donor and Recipient Informed Understanding in Practice.**

Studies of practice in medicine have raised concerns about the extent to which practitioners disclose and ensure understanding. Tom Beauchamp, in reviewing the literature (which he terms describes as a part of 'informed consent') has summarised the concerns,

"If informed consent means only telling things to an attentive patient, and not asking anything (such as questions or permission) of the patient, how are we to interpret claims by physicians that they regularly "obtain consents" from patients before medical procedures? The answer is that such claims are entirely unreliable unless we know the actual procedures involved in some detail. Matters may be even worse that they appear: perhaps all physicians understand by informed consent is that the patients signature was obtained, or perhaps they only mean that some kind of disclosure was made. This interpretation fits better with the results of studies of informed consent that proved more negative. Some studies failed to find any sizeable evidence of informed consent in clinical medicine; other studies found little

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<sup>5</sup>S.Schwartz, Elicitation of Moral Obligation and Self-Sacrificing Behaviour, *J Pers & Soc Psych*, 1970, 15(4), 283-293. The first of the three conditions is a sense of moral obligation to make the decision.



evidence that the consents obtained are meaningful exercises of informed choice by patients (Lidz and Meisel 1982,<sup>6</sup> 333-340; Faden and Beauchamp 1986, 98-100)."<sup>7</sup>

Beauchamp mentions one notable study<sup>8</sup> in which US physicians were asked, "what does the term informed consent mean to you?" Only 26% of physicians indicated that informed consent had anything to do with patients' giving permission, consenting, or agreeing to treatment; only 9% indicated that it involved patients' making a choice or stating a preference about his or her treatment, and recognition by the patient of what is taking place. It appears that most physicians surveyed only understood the informational aspect of informed consent.

Barnard has linked disclosure problems to the allopathic approach to medicine<sup>9</sup> His recommended solution is a "a more genuinely person-centred approach to illness and

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<sup>6</sup>'Informed Consent and the Structure of Medical Care.' in Presidents Commission 'Making Health Care Decisions,' *Washington D.C., Government Printing Office*, 1982.

<sup>7</sup>A History and Theory of Informed Consent, *Oxford University Press*, 1986. Some of the foremost cases in the United States have also adopted the position that informed consent is merely about information giving to the patient thus the U.S. Supreme Court in Planned Parenthood of Central Missouri v Danforth 426 US 52, 67 1976 stated that, "One might well wonder ...what 'informed consent' of a patient is... we are content to accept, as the meaning, the giving of information to the patient as to just what would be done and as to its consequences."

<sup>8</sup>Reviewed by T.Beauchamp in A History and Theory of Informed Consent, *Oxford University Press*, 1986.

<sup>9</sup>Barnard suggest that the allopathic model, "assumes a direct (even though frequently masked) correspondence between a person's subjective distress and underlying physiochemical bodily changes. From this perspective, the task of medical treatment is to translate the patient's subjective language of distress into the corresponding physical pathology, thus opening the way for appropriate intervention to return the physiochemical properties of the body to their premorbid state. In this account "illness" begins with the disruption in the physiochemical status of the body and ends when that status is returned to normal. The "meaning" of illness resides in the physician's categories for interpreting subjective distress in terms of underlying physiochemical conditions. These categories, when imposed on the patient's experience, lead to treatment recommendations which it is then the patient's responsibility to follow." (The Personal Meaning of Illness in Client-Centred Dimensions of Medicine and Health Care, Client-Centred Therapy, (ed) J.Shlien , 337-351 at 337). For more information on the client / person centred approach see Appendix 4. Barnard Adds that, "Many have argued that the biomedical model, when uncritically applied, carries several implications that detract from optimal medical care. First, the patient's own explanations and attributions concerning his or her illness are secondary in importance to the physician's, if they are even elicited or acknowledged at all. Indeed, the physician must substitute his or her explanations for the patient's as quickly as possible to ensure rational therapy. Second, the significance of the patient's symptoms is determined by the physician according to the inherent seriousness of the condition and the requirements of treatment. The biomedical model directs the physician's attention to the problem of accurate diagnosis and therapy, and not to personal or cultural meanings or associations that the patients may attach to their distress. Third, because illness consists in disturbed physiochemical processes, social and cultural factors are irrelevant in identifying and treating bodily disorders. There is no room in the strict biomedical model for the cultural patterning of illness, in which bodily complaints may express or represent culturally appropriate forms of coping with personal or social stress. Fourth, patients are assumed to consult the physician for the treatment of bodily complaints. In the absence of identifiable organic disease, the patients' requests and agendas in the consulting room are considered illegitimate, and the physician does not feel compelled to address them. Fifth, since presumably it is the physician and not the patient who understands the biomedical model and must apply it to solve the patient's problem, expertise, power



it's medical treatment"<sup>10</sup> involving a model of negotiation (see Figure 2). However, there must be doubt as to how far changes can occur without altering the whole paradigm of medicine;<sup>11</sup> conventional medicine functions primarily according to the idea that medical professionals can 'solve' medical problems in the same way as a mechanic might fix a malfunctioning car<sup>12</sup> and this manifests in the doctor typically assuming (and / or being treated as having) all or most of the authority in the relationship with the patient's role being to be uninvolved with the treatment and undemanding.<sup>13</sup>

**Figure 2: Barnard's Negotiation Model for Medical Practice**

"the client-centred hypothesis that person's themselves possess decisive healing resources. In the medical context, patients possess a positive potential for growth and health. Medical interventions and knowledge, in this perspective, are only one among many determinants of personal health. A major role of the physician is to assist the patient to reclaim or renew his or her own strengths and tendencies toward growth. In certain circumstances this may entail the application of technical modes of healing. In all cases, however, it will require the effort of helping the patient to clarify personal needs and goals, and to select, with the help of the physician, plans and actions consistent with and supportive of personal values."<sup>14</sup>

Given the theoretical and empirical evidence presented above, the hypothesis must be that excellent disclosure standards in LDT are unlikely. While some LDT studies have focused on the endpoint of informedness of donor consent,<sup>15</sup> the only empirical evidence directly relevant to this hypothesis is a study of 494 Norwegian donors by Westlie *et al.*,<sup>16</sup> and the multi-jurisdictional survey of donors and recipients conducted for this research in conjunction with EUROTOLD.<sup>17</sup>

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and authority in the doctor patient relationship are inherently and appropriately unequal. The physician diagnoses and recommends; the patient answers questions accurately and follows advice (Ibid at p338-339).

<sup>10</sup>Ibid at 337.

<sup>11</sup>Sociologically, the development of dialysis and transplantation (and hence LDT) can themselves be viewed as part of a wider problem of relatively unquestioning reliance on a model of medicine which by its very nature is not attuned to patient rights. If alternative, holistic, methods of treatment of serious forms of organ disease were further examined and shown to be more efficacious the protection of patient rights might be enhanced - indeed holistic approaches have long emphasised facilitation of client / patient autonomy and tend to be relatively free of the intractable problems relating to doctor-patient communication in conventional medical practice. The homeopathic approach, for instance, is based on a facilitative practitioner attitude (See H.Graham, *Introduction to Humanistic Psychology*, Open University Press, 1989).

<sup>12</sup>McLean, *A Patient Right To Know*, Dartmouth Publishing, 1989 at Ch1.

<sup>13</sup>Ibid at p4.

<sup>14</sup>Barnard *ibid* at 350-351.

<sup>15</sup>See chapter 7.

<sup>16</sup>L.Westlie, P.Fauchald *et al.*, Quality of Life in Norwegian Kidney Donors, *Nephrol Dial Transplant*, 1993, 8, 1146-1150. I had the pleasure of meeting the main author of this study, Dr



Westlie et al.'s study included an examination of 3 key disclosure issues: who provided information; the quantity of information provided; *and* the quality of information provided. The main providers of information about the process were nephrologists at the recipient's hospital and doctors and nurses at the national hospital; other sources, such as previous donor's, were relied on to a much lesser extent. A further question, asking whom the donor would seek information on kidney donation and transplantation from when it was wanted, revealed a heavy informational reliance on nephrologists at the recipient's hospital (90.3%).

This pattern of informational reliance on one person could be problematical in terms of getting the full range of information and perspectives on transplantation. Where dialysis is privately run<sup>18</sup> self-interest<sup>19</sup> could be a distorting factor in information disclosure by nephrologists.

In terms of quantity of information, most donors felt they had received enough information but some were unsure or felt they had insufficient information on a number of subjects (see Figure 3). In particular, this was the case for longer term information about post-operative recovery.

**Figure 3: Norwegian donor perceptions on whether they received enough information (Westlie et al.'s Study).**

*Received enough information on:*

how you were selected as a donor?	yes 83.1%	both yes&no10.2%	no 6.7%
what surgery would be like?	yes 70.6%	both yes&no 20.3%	no 9.1%
what post surgery hospitalisation would be like?	yes 51.7%	both yes&no 26.5%	no21.7%
what your recovery at home would be like?	yes 45.3%	both yes&no 23.5%	no 31.2%
chances of success for recipient were?	yes 71.8%	both yes&no 18.8%	no 9.4%

In terms of quality of information provided, a high percentage of donors were not fully enthusiastic: 35.9% said quality was 'acceptable' and 11.8% said it was not very helpful, 1.9% saying it was not helpful at all.

Lars Westlie, in Fredrikstad, Norway where I was able to discuss the study with him at some length and was given the comprehensive materials detailing methods and results which have now been summarised in the above article.

<sup>17</sup>See chapter 9.

<sup>18</sup>E.g. Germany

<sup>19</sup>In other words financial profitability from keeping people on dialysis.



In Westlie's study perceptions of disclosure could be summarised as ranging from poor to very good - it could best be described on the whole as average in terms of quality and quite good in terms of quantity. Further research is needed to establish firm conclusions but it may be tentatively theorised that disclosure to donors is better than to patients in general. A similar conclusion can tentatively be drawn from the donor and recipient interviews conducted for this research in conjunction with EUROTOLD (chapter 9.3.2); these interviews revealing illuminative subjective experiences of disclosure in LDT and indicate that practice is still far from ideal.

The other aspect relating to disclosure and informed understanding is how decisions are made in practice. There is a tendency for prospective donors and recipients to become acquainted with the significant factors involved in organ LDT over a period of time - it is fortunate in this respect that donors, at least, are not usually asked to make a decision about donation until a number of (reasonably time consuming) tests have been gone through. However, incremental consideration of the issues involved will not necessarily mean a readiness to immediately decide what one truly wants to do when asked. In this context empirical evidence about the way donors make decisions is disturbing. Fellner and Marshall have stated that,

"when a person is faced with a decision between two alternatives his behaviour is expected to be oriented toward making an objective and impartial evaluation of the merits of the alternatives. This usually takes the form of information seeking which probably continues until sufficient confidence is acquired that the preference will not be upset and reversed by subsequent information. At this level of confidence the rational person then will make a decision (pre-decision process).

Contrary to this expectation, we found that our donors made an immediate major decision, before even inquiring into the possible consequences for themselves, or seeking reassurance as to the eventual benefits for the recipient."<sup>20</sup>

Corroborating this conclusion, the studies of Simmons *et al.* in *The Gift of Life*<sup>21</sup> found that 88% of donors first considered donating as soon as they found out about

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<sup>20</sup>Twelve Kidney Donors, *J Am Med Assoc*, 1968, 206, 2703-2707 at 2706.

<sup>21</sup>*Gift of Life*, Wiley and Sons, 1977 at 431-3.



the need, 78% knew right away that they would definitely do it<sup>22</sup> and 61% followed a non-deliberative model of decision-making<sup>23</sup> with only 5% postponing decisions indefinitely or to the last minute.<sup>24</sup> In addition the donor and recipient questionnaires conducted for this research in conjunction with EUROTOLD indicate immediate decision-making by donors to be the norm.<sup>25</sup>

Fellner and Marshall's conclusion that informed consent in living donation is a myth<sup>26</sup> is supported not just by the speed of decision-making but also by empirical studies suggesting that donation is in some cases unconsciously motivated rather than based on a rational assessment of all the relevant factors. Whilst donors tend to be highly motivated,<sup>27</sup> and unconscious aspects should not be overestimated<sup>28</sup> problems are very clearly present and in their light it has been stated that the physicians responsibility to safeguard the rights and responsibilities of the donor is of vital importance.<sup>29</sup>

### **5.3. Law Relating to Disclosure and Informed Understanding in Organ LDT.**

#### **5.3.1. General Issues.**

International guidelines have taken contrasting approaches to the issue of donor disclosure. The Third Conference of European Health Ministers in Paris (16-17 November 1987) emphasises a range of specific categories of information that must be disclosed without commenting on the depth of disclosure or its function,

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<sup>22</sup>Ibid at 242.

<sup>23</sup>Ibid at 244. 25% had a period of deliberation with a conscious choice.

<sup>24</sup>R.G.Simmons et al., *Gift of Life, Transaction Books*, 1987.

<sup>25</sup>Chapter 9.

<sup>26</sup>C.Fellner and J.Marshall, *Kidney Donors - The Myth of Informed Consent*, *Am J Psych*, 1970, 126, 1245-1251.

<sup>27</sup>J.Shanteau and J.Skowronski, *The Decision to Donate Organs* in J.Shanteau et al., *Organ Donation and Transplantation: Psychological and Behavioural Factors*, *Am Psych Ass*, 1991, 59-67. Simmons et al., *Gift of Life, Wiley and Sons*, 1977.

<sup>28</sup>Simmons et al., *Gift of Life, Wiley and Sons*, 1977.

<sup>29</sup>Ibid at 2707.



"the donor should be given appropriate information before the removal about its possible consequences, in particular the medical, social and psychological effects, as well as about the implications of the donation for the recipient."<sup>30</sup>

On the other hand the World Health Organisation's Guiding Principles on Transplantation emphasise disclosure simply in the context of knowing and evaluating the significance of giving consent - with Guiding Principle 3 stating that,

"the donor should be.. sufficiently informed to be able to understand and weigh the risks, benefits and consequences of consent."<sup>31</sup>

Such guidelines, along with most pieces of transplant legislation<sup>32</sup> do not consider the matter of professional responsibilities to disclose information to recipients. Where the recipient is considered it is typically in a less comprehensive manner than consideration of the donor. However, interestingly regulation of disclosure to donors can also be limited e.g. to particular classes of donor;<sup>33</sup> UK law, only regulates disclosure in relation to donors not legislatively classed as genetically related to the recipient<sup>34</sup> while Hong Kong<sup>35</sup> law only regulates disclosure where the donor is not legislatively classed as genetically related to the recipient and not the recipient's spouse of 3 or more years standing.<sup>36</sup> There are also a few jurisdictions where transplant law does not examine disclosure in LDT at all including; Cuba,<sup>37</sup> Ecuador,<sup>38</sup> Kuwait,<sup>39</sup> Syrian Arab Republic<sup>40</sup> Uruguay,<sup>41</sup> Vietnam,<sup>42</sup> Zimbabwe<sup>43</sup>

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<sup>30</sup>Adopted as para 11. of The Council of Europe Recommendation No.R (79) of The Committee of Ministers to the Member States. Reprinted in the World Health Organization's Book, 'Legislative Responses To Organ Transplantation,' *Martinus Nijhoff*, 1994, Appendix 1.

<sup>31</sup>WHO Guiding Principles 1991, adopted by the World Health Assembly in resolution WHA44.25. Reprinted in 'Legislative Responses To Organ Transplantation,' *Martinus Nijhoff*, 1994 at Appendix 1. See also Human Organ Transplantation: A Report on Developments Under the Auspices of WHO (1987-1991) WHO 1991.

<sup>32</sup>Exceptions are Belgium, Finland, Poland, Spain and Turkey plus those discussed in the following sections.

<sup>33</sup>Disclosure requirements can also be limited by the relevant legislation only covering certain organs - e.g. Italian legislation only covers kidneys.

<sup>34</sup>See HOTA 1989 section 2(3) - discussed at section 4

<sup>35</sup>Ordinance No 16 of 1995.

<sup>36</sup>Indian law also imposes disclosure requirements only for certain classes of donor (see Act No. 42 of 1994, *IDHL*, 1995, 46(1), 34-38.

<sup>37</sup>Decree No. 139 of 4 February 1988 at section 80.

<sup>38</sup>Law No. 64 of 26 May 1987 Reforming the Health Code.

<sup>39</sup>Decree Law No. 55 of 20 December 1989.

<sup>40</sup>Law No. 31 of 23 August 1972 On the Removal and Transplantation of Organs from the Human Body at section 2(3). Peru may be a further exception but the full text of its recent law has yet to be published in English (for a limited text see *IDHL*, 1994, 45(1), 36-37).

<sup>41</sup>Decree No. 660/991 of 4 December 1991 at section 4.

<sup>42</sup>Law of 30 June 1989 On the Protection of Public Health at section 30 subsections 1 and 3 respectively.



plus a few regimes (e.g. Austria and Malaysia) that are simply limited in ambit to cadaveric donation.

Roughly parallel with the development of transplant legislation, there has been a wide-ranging development of general law relating to disclosure in medical treatment in many common and civil law jurisdictions;<sup>44</sup> such law being capable of application to living organ donation and reception. The contrast between general principles and regulation in transplant legislation is interesting. Whilst the latter tends to promote certainty and professional awareness on some disclosure matters it is a long way from being comprehensive. For instance, only a minority of transplant laws specify disclosure requirements for the recipient and most lack fail to indicate what depth of information must be given.

Transplant laws in Belgium<sup>45</sup> and many Australian<sup>46</sup> states, supplant some of the original role of general principles of law (the failure to meet legislative disclosure requirements precludes the giving of a valid consent to donation which is actually defined in terms of professional responsibilities laid out in the legislation<sup>47</sup>). However, in most cases legislation is merely a supplement to general principles. For instance, in Algeria,<sup>48</sup> Norway,<sup>49</sup> Costa Rica,<sup>50</sup> satisfaction of legislative disclosure requirements simply acts as a gateway that must be passed through if valid consent, as defined by general principles, is to be given. In U.K. law, liability can flow from both under principles of negligence / battery *and* under the provisions of HOTA 1989.<sup>51</sup> In this type of situation the failure to meet a legislative requirement has no special bearing on the legal validity of consent to donation. Indeed, common law principles will probably be used to define consent under the Act; regulation 3(2)b of The Human Organ Transplants (Unrelated Persons) Regulations 1989 (SI No. 2480) refers to ULTRA needing to be satisfied that the donor has understood *and*

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<sup>43</sup>Anatomical Donations and Post Mortem Examinations Act No. 34 of 1976 at section 12(a).

<sup>44</sup>See D.Gieson, *International Medical Malpractice Law*, J.C.B. Mohr (Paul Siebeck) and Martinus Nijhoff, 1988, paras 486-514, 550-669, 1132, 1164-1177, 1181-2001.

<sup>45</sup>Law of June 13 1986 at section 8.

<sup>46</sup>For example see Northern Territory Act No 121 of 1979 at section 10 and Queensland, The Transplantation and Anatomy Act 1979-84 at section 10. See also Legislative Responses to Organ Transplantation at 13-131.

<sup>47</sup>However, a claim in negligence for insufficient disclosure may still be open in this situation.

<sup>48</sup>Law No. 85-05 of 1985 at section 162.

<sup>49</sup>Law No. 6 of 9 February 1973 at section 1

<sup>50</sup>Law No. 5560 of 20 August 1974 at section 15.

<sup>51</sup>Some other examples of this include Bolivia (section 11 March 1982 law), Colombia (Decree No. 1172 of 6 June 1989 at section 35e), Cyprus (Law No. 97 of 1987 at section 7), Lebanon (Decree No. 109 of 1983), Mexico (Federal Regulations of 16 August 1976 at section 31V), Kuwait (Decree Law No. 55 of 20 December 1987 at section 4), Panama (Law No. 10 of 11 July 1983 at section 6), Russian Federation (Law of 22 December 1992 at section 6) and Denmark (Law No. 402 of 13 June 1990 at section 13(3)).



consented in order to grant authorisation i.e. the term 'understanding' is *not defining* consent, which is nowhere defined within the legislative regime. While the Act considers the matter of disclosure and understanding in LDT's defined as 'non-genetically related,' it appears that regardless of whether a doctor had proceeded with or without ULTRA authorisation for a 'non-genetically related donation' (s)he could theoretically be liable in negligence or battery for disclosure (and, incidentally, technical) failures. Occasionally transplant legislation merely acts to confirm general principles - e.g. laws in Uruguay,<sup>52</sup> Peru,<sup>53</sup> Zimbabwe,<sup>54</sup> Vietnam,<sup>55</sup> and the Syrian Arab Republic<sup>56</sup> merely state that the express consent of the donor is required in LDT.

### **5.3.1.1. The Tort of Battery**

The first problem with general principles of law has been that they rarely promote high standards of disclosure. In the case of common law, this is due to relying on the tort of negligence to define disclosure requirements. It having been held that a practitioners failures (even if gross<sup>57</sup>) to explain risks and benefits will not make consent unreal,<sup>58</sup> use of the tort/crime of battery is confined to situations like agreeing to one procedure and a different one being performed<sup>59</sup> or the practitioner being aware that the patient did not understand the nature of the procedure intended<sup>60</sup> or acting in bad faith<sup>61</sup> rather than being the outcome of a failure to provide and communicate information sufficiently to support an autonomous independent decision.<sup>62</sup>

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<sup>52</sup>Decree No. 660/991 of 4 December 1991 at section 4.

<sup>53</sup>Supreme Decree No. 014-88-SA of 19 May 1988 at section 15 repealing Law No. 23415 of 1 June 1982.

<sup>54</sup>Anatomical Donations and Post Mortem Examinations Act No. 34 of 1976 at section 12(a).

<sup>55</sup>Law of 30 June 1989 On the Protection of Public Health at section 30 subsections 1 and 3 respectively.

<sup>56</sup>Law No. 31 of 23 August 1972 On the Removal and Transplantation of Organs from the Human Body at section 2(3).

<sup>57</sup>Hills v Potter [1983] 3 All ER 716 Hirst J 3 All ER 716. "The plaintiff's undoubted consent to the operation which was in fact performed negates any possibility of liability under this head." Confirmed by the Court of Appeal (and by Lord Scarman in the House of Lords) in Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital [1985] 1 All ER 643 per Sir John Donaldson and Lord Justice Dunn. This position has also been reached in Canada (see Reibl v Hughes [1980] 114 D.L.R. (3d) 646 Supreme Ct of Canada) although cases like Koehler v Cook [1975] D.L.R. (3d) 766 and Zimmer v Ringrose [1978] 89 D.L.R. (3d) 646 have criticised this approach.

<sup>58</sup>Chatterton v Gerson [1981] Q.B. 432 at 442G.

<sup>59</sup>Ibid and Cull v Royal Surrey County Hospital and Butler, *Br.Med.J.*, 1932, 1, 1195. Or consent given to a particular surgeon and another surgeon performed the operation (provided that the consent and authorisation was legitimately confined to one such surgeon - which today, outside of private medicine, is unlikely).

<sup>60</sup>Chatterton v Gerson [1981] QB 432.

<sup>61</sup>Or where a person touches without consent in a case where only a specific other persons touching is consented to in a case where the identity of the person affects what is being done.

<sup>62</sup>An example of the limits of the current approach would be where a doctor recommending a drug to a patient provides no information as to the fact it may have side effects, with the result that the patient



However, by way of exception, failure to meet required disclosure standards will found an action in battery where a procedure is experimental and non-therapeutic as established in the Canadian case of Halushka v University of Saskatchewan [1965] 53 DLR (2d) 436. This exception, is justified on the basis that the ethical principles governing experimental research make confining recovery to negligence unacceptable in experimental research/non-therapeutic situations.<sup>63</sup> What apparently discounts the recipient from using the battery head is the fact that organ donation is always therapeutic (at least if done within principles of ethics, and sometimes law). However, donors undergoing forms of donation that are experimental should be treated under the head of battery on the basis that the procedure is not justified in itself as for the therapeutic benefit of the donor even if in some cases the donor might gain more benefit than detriment out of it (as indeed might somebody partaking in medical research not designed to benefit them).

While Zimmer v Ringrose [1981] 28 A.R. 69, (1981), [1981] 4 W.W.R. 75 (C.A) concluded that use of the battery analysis in disclosure cases is limited to the non-therapeutic experiment context, there must be hoped that it could be more widely applied in the unique situation of LDT. Gieson has suggested that,

“as regards the donor, extensive and detailed information must be required since no therapeutic treatment of him is intended and thus he will not therapeutically benefit from the operation.”<sup>64</sup>

Under a framework of common law, the need for disclosure of detailed and extensive information necessitates sole reliance on the battery analysis, simply because, under the tort of negligence a practitioner could escape unsanctioned for non-disclosure simply on the basis that the donor would still have gone ahead with the procedure had the legally required level of disclosure taken place (see below). As already reasoned, the recipients unique interdependence with the donor also warrants that (s)he receives extensive and detailed information, again requiring sole reliance on the tort of battery. Despite it's rationality this approach is likely to generate some unease, particularly in

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may end up assenting and forming a *legally valid consent* to a treatment without making an informed autonomous decision and so arguably *not consenting* in the fundamental *ethical* sense of the word.

<sup>63</sup>Gieson, Civil Liability of Physicians for New Methods of Treatment: A Comparative Examination, *Med Law Review*, 1995 (Spring), 3, 22-52 at 33.

<sup>64</sup>International Medical Malpractice Law, *J.C.B.Mohr (Paul Siebeck) & Martinus Nijhoff*, 1988, 609.



those jurisdictions which are used to restricting disclosure requirements in the interests of restricting the scope of liability of medical practitioners.<sup>65</sup>

### 5.3.1.2. The Tort of Negligence

The intrinsic problem with using negligence to define disclosure requirements, both in general and in LDT, is that even if the relevant standard is breached the onus is on the patient to prove causation i.e. that on the balance of probabilities that (s)he would not have undergone the procedure if the relevant disclosure standard had been met.<sup>66</sup>

This basically means that inadequate disclosure, even failure to disclose very significant risks can go without legal sanction simply because a patient/recipient/donor cannot prove (s)he would have made a different decision if the disclosure standard had been met.

Even with use of a subjective test,<sup>67</sup> most patients will find it difficult to *find* the evidence to show that if (s)he had received proper disclosure a different decision would have been made. In practice whatever a patient may subjectively suggest (s)he would have done a judge is likely to apply his own standard of rationality to the

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<sup>65</sup>For instance, several judgements have indicated that English disclosure requirements under the tort of negligence are motivated by a desire to restrict liability (on grounds of policy rather than principle). Lord Denning in Hatcher v Black [1954] Times 2 July conjures up visions of MacBeth in suggesting that expanding liability would result in the doctor or surgeon, "instead of getting on with his work.. forever looking over his shoulder to see if someone was coming up with a dagger." Lord Scarman in Sidaway alluded to, "the danger of defensive medicine developing in this country[1985] 1 All ER 643 a sentiment echoed by Lord Justice Mustill in Wilsher v Essex Area Health Authority [1987] QB 730, [1986] 3 All ER 801 (CA) who stated that "the risks which actions for professional negligence bring for the public as a whole, in the shape of an instinct on the part of the professional man to play for safety, are serious and are now well recognised. Of course one can argue on grounds of principle that failing to disclose is itself a form of defensive medicine ("Failure to challenge the practice of medical practitioners even in the routine situation has led, or may lead, to general societal unwillingness to challenge other aspects of medicine." McLean, A Patients Right to Know, *Dartmouth Publishing*, 1989, 102) and that requiring higher standards would simply encourage a more enlightened approach to doctor-patient interaction (one that in itself might reap benefits in the healing process - see Barnards comments about a person centred approach in section 5.2).

<sup>66</sup>A duty will normally exist to patients (see Barnett v Chelsea and Kensington Hospital Management Committee [1969] 1 QB 428 [1968] 1 All ER 1068 (QBD) and generally see M.Brazier (ed) *Medicine, Patients and the Law*, *Penguin*, 1992 (2nd Ed), 117-118). While the donor is not a patient a duty would normally exist to him or her also.

<sup>67</sup>In Reibl v Hughes [1980] 114 DLR (3d) 1 (Can Sup Ct) an objective test was used for causation - i.e. based on whether or not a reasonable patient would have gone ahead with a procedure. This is clearly absurd because causation is a matter based on the facts of what would have happened not an abstracted notion of reasonableness. The objective test in Reibl has not surprisingly been rejected in favour of a subjective approach in several jurisdictions including English (Chatterson v Gerson [1981] QB 432 per Bristow J obiter) and New South Wales (Ellis v Wallsend District Hospital [1989] 17 NSWLR 553 (NSW CA))



situation in the absence of very strong evidence of what the patient would have done.<sup>68</sup>

Added to this intrinsic problem of proving causation, Eire<sup>69</sup> and, in general, the US<sup>70</sup> have followed English law in restrictively defining the standard of disclosure that is required by the practitioner to meet his or her duty of care under the head of negligence. The key case is Sidaway v Board of Governors, Bethlem Royal Hospital [1985] AC 871 where the majority in the House of Lords confirmed that in English law the duty of care is met where a doctor acts in accordance with a school of thought accepted as proper by a responsible body of medical opinion.<sup>71</sup> Whilst a number of cases<sup>72</sup> have interpreted Sidaway as denying the possibility of judicial scrutiny of reasonableness where there is expert evidence available,<sup>73</sup> it is clear that a practice defined as reasonable by a competent body of medical opinion *could* still be negligent in exceptional circumstances.<sup>74</sup> However, the level of duty remains not

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<sup>68</sup>This is classically illustrated in the recent case of Poynter v Hillingdon (High Court, 23 April 1997, unreported) where despite the clear evidence that parents considering treatment for their child were very much against an allopathic approach - agreeing to it with extreme reluctance (perhaps even coercion), Sir Maurice Drake viewed matters very much in terms of *he himself* considering the allopathic treatment proposed to be in the best interests of the child and deriving from this a conclusion that the parents would have consented to such treatment on the child's behalf even if the relevant non-disclosed informations concerning risks had been disclosed. One can see the danger here that in effect disclosure negligence will in most instances be limited to cases where the patients best interests are gone against according to the court and hence (s)he finds no problem in persuading the court that (s)he would have made a different decision had the relevant disclosures taken place.

<sup>69</sup>Dunner v National Maternity Hospital [1988] IR 91

<sup>70</sup>See Mason & McCall-Smith, *Law and Medical Ethics*, Butterworths, 1991, 245.

<sup>71</sup>Declaration in Bolam v Friern Hospital Management Committee [1957] 2 All ER 115 followed and approved in both cases of treatment (see Whitehouse v Jordan [1981] 1 WLR 246 - particularly per Lord Edmund Davies at 258 (HL)) and in cases of diagnosis (see Maynard v West Midlands Regional Health Authority [1984] 1 WLR 634 - particularly per Lord Scarman at 638). The approach in Sidaway has been confirmed as good law several times subsequently including by the Court of Appeal in Hughes v Waltham Forest HA [1991] 2 Med LR 155.

<sup>72</sup>Including Gold v Haringey Health Authority [1987] 2 All ER 888 (albeit in the context of alternative treatments rather than risks of treatment), Palmer v Eadie (18 May 1987, unreported), CA and Blyth v Bloomsbury HA [1993] 4 Med LR 151 CA.

<sup>73</sup>The Court of Appeal in Joyce v Merton Sutton and Handsworth Health Authority 27 BMLR 124-157 (applying Bolam) held that only limited weight will be given to the defence of practitioners that they had followed *their* normal practice if there are witnesses and documentary evidence showing that proper practice was not followed and no other expert medical evidence in favour of the defence.

<sup>74</sup>Court of Appeal in Bolitho v City Hackney HA [1993] 13 BMLR 111 (stating that there is a 'very onerous weight' on the plaintiff to show conventional practice is unreasonable). This approach is supported by a close analysis of Lord Bridge's judgement in Sidaway, "even in a case where, as here, no expert in the relevant field condemns the non-disclosure as being in conflict with accepted and responsible medical practice, I am of the opinion that the judge might in certain circumstances come to the conclusion that disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it" (Sidaway [1985] AC 871, [1985] 1 All ER 643 at 663). This approach was subsequently applied in Smith v Tunbridge Wells HA [1994] 5 Med LR 334 (QBD) where Morland J, faced by medical evidence that it would not have been common practice to have disclosed a particular risk but, held that, "although some surgeons may still not have been warning patients similar in situation to the plaintiff of the risk....that omission



defined by equal reference to expert opinion from both sides<sup>75</sup> but through an overwhelming deference to expert evidence of a group of practitioners selected on behalf of the defence, belonging to a profession not noted for its high disclosure standards from whence the very alleged abuses of patient rights came.<sup>76</sup>

A problem generally, and in the specific context of LDT is that adopting this so-called 'professional based standard'<sup>77</sup> is bound to impact on the way the profession behaves<sup>78</sup> including fostering the unquestioning acceptance of the authority of medicine which to some extent already exists.<sup>79</sup> Not surprisingly this approach has

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was neither reasonable nor responsible" (p339). He clearly viewed this as "applying the *Bolam* Test as elucidated in *Sidaway*." (p339). The House of Lords have now ruled in *Bolitho* ([1997] All ER 4, 771 HL.) that where there are two bodies of opposing opinion the one brought forward for the defence can be rejected (even if competent) if it is not logically supportable (p779). *Hucks v Cole* (1968)(1993) 4 Med LR 393 was applied to conclude that medical opinion could be rejected where it did not stand up at all to logical analysis. Lord Brown-Wilkinson, giving the judgment, stressed that this would seldom occur. Commenting on the decision the All ER Annual Review 1997 concludes at p314 that, "*Bolitho* represents an adaptation of *Bolam* rather than a radical break....It will be used sparingly by the courts."

<sup>75</sup>As would be the case in most non-medical areas of negligence.

<sup>76</sup>As McLean states English law places an "almost overwhelming weight placed on medical judgement and the deference shown to orthodox medicine and its therapies (Sheila McLean, *A Patients Right to Know*, *Dartmouth Publishing*, 1989, 103).

<sup>77</sup>In *Sidaway* Lord Diplock gave unequivocal approval to the *Bolam* test and suggested it was the doctor's function to weigh and evaluate options, not the patients, "all these are matters which the doctor will have to take into consideration in determining, in the exercise of his professional skill and judgement, that it is in the patients best interests that he should take the risk involved and undergo the treatment recommended by the doctor." *Sidaway* [1985] 1 All ER 643 at 656. Avoiding negligence was simply showing that a responsible body of medical opinion would have taken the course taken by the defendant. He rejected the view that the determining factor should be the patient's level of informedness. Informed consent appears to have been used loosely here rather than in its technical sense as a legal doctrine. For discussion of the doctrine of informed consent see Mason & McCall-Smith, *Law and Medical Ethics*, *Butterworths*, 1991, p242-252. As Dunn LJ stated in the Court of Appeal in *Sidaway*, "the doctrine of informed consent forms no part of English law" (*Sidaway* [1985] 1 All ER at 517 (CA)). Lord's Bridge and Keith adopted the *Bolam* test while contradictorily asserting the paramount nature of patient autonomy ([1985] 1 All ER 643). Lord Templeman emphasised that the patient did not need to be told of all the risks; "the doctor ... must decide what information should be given to the patient and in what terms that information should be couched" [1985] 1 All ER 643 at 666. This point would suggest that any doctrine of therapeutic privilege would be merely superfluous - a viewpoint noted by Kennedy and Grubb, *Medical Law: Text with Materials*, *Butterworths*, 1994, 211. Kennedy and Grubb discuss the case of *Blyth v Bloomsbury Health Authority* [1993] 4 Med LR 151 (CA) in relation to the issue of a doctor's duty to answer questions that are directly asked by a patient (*Medical Law: Text With Materials*, *Butterworths*, 1994, 205-211. The opportunity to create more stringent requirements for disclosure, communication and understanding than for the exercise of technical skills was missed in all 4 majority judgements [1985] 1 All ER 643 at 657. This confirms the approach in *Hatcher v Black* (1954) Times, 2 July (QBD) and *Bolam*.

<sup>78</sup>Klass has suggested it is one reason for the huge (in his view excessive) prescription of drugs in the United Kingdom (See A.Klass, *There's Gold in Them Thar Pills*, *Penguin*, 1975).

<sup>79</sup>"The idea of questioning, not to speak of refusing a doctor's order is difficult for patients to contemplate, if not out of habit then out of other concerns. For example, patients often feel compelled to surrender their right to ask questions out of fear of offending their doctors and out of guilt about imposing on their own time." Katz, *The Silent World of Doctor and Patient*, 1986, p. x.



received criticism by academics<sup>80</sup> and the judiciary,<sup>81</sup> not least because it limits the role of patient autonomy,

"where doctors are allowed to limit disclosure on the basis of their clinical judgement the patient's capacity to make decisions based upon his own value commitments and weighting of the various risks is undermined."<sup>82</sup>

Fortunately, a number of jurisdictions including Canada,<sup>83</sup> some Australian states,<sup>84</sup> New Zealand,<sup>85</sup> South Africa<sup>86</sup> and a number of leading civil law jurisdictions such as Switzerland, Austria and Germany<sup>87</sup> have rejected use of a 'professional based standard' in favour of one based on the disclosure needs of the 'reasonable patient' in the actual patient's situation. Underlying this approach, according to the Australian High Court in Rogers v Whittaker [1993] 4 Med LR 79, is,

"...the principle that, while evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of

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<sup>80</sup>See for instance M.Brazier, Patient Autonomy and Consent to Treatment: The Role of the Law? *L.S.*, 1987, 7, 169; D.Gieson and J.Hayes, The Patients Right to Know - A Comparative Analysis, *Anglo Am Law Rev*, 1992, 21, 101; D.Gieson, Vindicating the Patient's Rights: A Comparative Perspective, *Journal of Contemporary Health Law and Policy*, 1993, 9, 273-309.

<sup>81</sup>See Bollen J in the Supreme Court of Australia decision of F v R [1983] SASR 189 and the Australian case of Rogers v Whittaker [1992] 175 C.L.R. 479. See the Supreme Court of Ireland in the case of Dunne v National Maternity Hospital [1988] IR 91. Sidaway has been applied to assume that the patient already has knowledge of certain things (Thake v Maurice [1986] Q.B. 644).

<sup>82</sup>Per Lord Scarman in his minority judgement in Sidaway [1985] 1 All ER 643 (at 654) where he also stated that, "it would be a strange conclusion if courts should be led to conclude that our law, which undoubtedly recognises the right of the patient to decide whether he will accept or reject the treatment proposed, should permit the doctors to determine whether and in what circumstances a duty arises, requiring the doctor to warn his patient of the risks inherent in the treatment which he proposes" (Sidaway [1985] 1 All ER 643 at 649). His Lordship's approach drew heavily on such an informed consent approach used in Canterbury v Spence [1972] 464 F 2d 772, US App DC; cert denied 409 US 1064 and differentiated between technical and non-technical aspects of medicine to assert that the doctors duty to inform stems from the patient's rights {1985] 1 All ER 643 at 654. However, in the final analysis the judgement was very qualified by a defence of 'therapeutic privilege.'

<sup>83</sup>*Ibid* at 245.

<sup>84</sup>See for instance the New South Wales Court of Appeal Decision of Ellis v Wallsend District Hospital [1990] 2 Med LR 103 and the decision of the Australian High Court in Rogers v Whittaker [1993] 4 Med LR 79.

<sup>85</sup>See particularly the New Zealand Court of Appeal decision of Smith v Auckland Hospital Board [1964] NZLR 241.

<sup>86</sup>See particularly Castell v De Greef (1994) Case No. A 976/92 (Supreme Court of South Africa, Cape of Good Hope Provincial Division, per Ackermann J.) (not yet reported).

<sup>87</sup>These are cited by Gieson's comparative analysis of world-wide provision in this area of law (see D.Gieson, From Paternalism to Self Determination to Shared Decision-Making, *Acta Juridica*, 1988, 107; D.Gieson and J.Hayes, The Patients Right to Know, A Comparative Analysis, *Anglo American Law Review*, 1988, 2, 101; D.Gieson, Vindicating the Patient's Rights: A Comparative Perspective, *The Journal of Contemporary Health Law and Policy*, 1993, 9, 273-309; D.Gieson, Civil Liability of Physicians for New Methods of Treatment and Experimentation: A Comparative Examination, *Med Law Review*, 1995 (Spring), 3, 22-52).



care after giving weight to “the paramount consideration that a person is entitled to make his own decisions about his life.””<sup>88</sup>

### **5.3.2. Depth and Range of Disclosure in LDT**

#### **5.3.2.1. General Points.**

As already stated,<sup>89</sup> in order to avoid the perils of proving causation LDT must be considered under the head of battery. However, whatever test is used the range and depth of disclosure to donors is likely to be exceptionally high. Whilst Lloyd LJ in Gold v Haringey Health Authority [1987] 2 All ER 88<sup>90</sup> felt that making a legal distinction between therapeutic and non-therapeutic procedures would go against the whole thrust of the House of Lords decision in *Sidaway*, the fact that donation is a non-therapeutic procedure will surely influence disclosure requirements. It would be difficult to justify treating the recipient in anything but the same fashion here because his/her unique interdependence with the donor necessitates making a choice based on all significant information irrespective of whether (s)he and/or the medical practitioner want information disclosed.

The nature of disclosure in organ LDT will, however, vary according to a number of factors including:

1. the test for disclosure being applied (i.e. based on the reasonable patient or a more professional based standard);
2. any enhanced factors in the specific situation such as due to limited hospital expertise or equipment or due to a particular make-up of one of the participants (e.g. a donor having the onset diabetes or high blood pressure);
3. the specific organ being donated; *and*

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<sup>88</sup>At 82 citing King CJ in *F v R* (1983) 33 SASR 189.

<sup>89</sup>See 5.3.1.1.

<sup>90</sup>Giving the judgment of the Court of Appeal (Watkins and Stephen Brown LJJ agreed) reversing the view of the trial court.



4. the extent to which the procedure is experimental i.e. yet to be proven as the optimum treatment and/or unpredictable in prospective detriment/ benefit levels.<sup>91</sup>

#### Professional Disclosure Test.

Whilst a competent body of medical opinion brought forward by the defence will *normally* determine disclosure requirements under a professional based test certain factors would surely have to be disclosed in living organ donation irrespective of such opinion. Skegg has stated that,

“if a doctor involved in renal transplantation failed to disclose the risks of nephrectomy to a potential living donor, before obtaining his consent to the removal of one of his kidneys a judge would be virtually certain to hold that the doctor was in breach of his duty of care to the donor, even if (which is not the case) the doctor could adduce evidence that his conduct was in accord with a common and professionally approved practice”<sup>92</sup>

This approach could be applied equally to the recipient. It must also be the case that a practitioner, as well as being required to disclose any significant risks to the donor and recipient, would be required to disclose any significant benefits. Expectations of the *range* of disclosure beyond medical risks and benefits must be limited because as Lord Scarman noted, a doctor may only be partially, if at all, aware of the ‘non-medically oriented’ factors that bear on the patient’s decision, “for example, his family, business or social responsibilities.”<sup>93</sup> Nevertheless, these non-medically oriented factors are particularly relevant to LDT for both the donor and recipient (for instance the potential economic consequences of donation, potential family stress etc.) a reasonable practitioner would make some effort at disclosure of some of the factors beyond the purely medical while not meeting, for example, the standards of a

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<sup>91</sup>In this context *F v R* [1983] 33 S.A.S.R. 437 (F.C.) evaluated disclosure as influenced by the degree of speculativeness and haphazardness in the procedure whilst Gieson has stated that the degree of novelty will be influential (Civil Liability of Physicians for New Methods of Treatment and Experimentation: A Comparative Review, *Med Law Review*, 1995 (Spring), 3, 22-52 at 35).

<sup>92</sup>Skegg, *Law, Ethics and Medicine*, Oxford University Press, 1984, 85.

<sup>93</sup>Sidaway [1985] 1 All ER 643.



social worker, family therapist or financial advisor. However, whether it would be a legal duty to make some effort in this area is debatable given that a competent body of medical opinion could probably be brought forward to support non-disclosure of such information's as common practice.

Although the nature of the professional based reasonableness test makes it impossible to accurately prophesise what must be disclosed in a given situation such as LDT, there are useful obiter-dicta 'hints' or 'guidelines' which can be applied. In English law part of the problem is that these 'hints' are quite variant in nature. Lord Bridge in *Sidaway* said certain risks would have to be disclosed irrespective of medical opinion.<sup>94</sup> He suggested that substantial risks of grave adverse consequences (such as 10% chance of a stroke) must be disclosed.<sup>95</sup> Under this test the donor and recipient might be able to expect information about such things as:

- risks for the recipient of rejection, the possibility of very serious cumulative side effects from drugs and the possibility of sexual dysfunction (such as impotence) plus any other serious risks applying in reception of a specific type of organ (e.g. lung lobe).
- risks for the donor of any substantial risks of grave adverse consequences such as the risk of donor splenectomy in liver segment donation risk of donor splenectomy and loss of endocrine and exocrine function in pancreatic vessel length donation.<sup>96</sup>

Lord Templeman felt that 'special' dangers particular to the operation would have to be disclosed.<sup>97</sup> Given his Lordship's medically deferential speech<sup>98</sup> such special dangers would probably have to be significant to be disclosed - perhaps, in the case of LDT disclosure of such things as:

- risk to the recipient of rejection, drug side effects, effects on family life and impact on sexual function etc.;

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<sup>94</sup>[1985] 1 All ER 643 at 663.

<sup>95</sup>*Ibid.*

<sup>96</sup>See chapter 3.4. for further discussion of risks in particular forms of LDT.

<sup>97</sup>*Ibid.*

<sup>98</sup>Kennedy and Grubb, *Medical Law: Text With Materials*, Butterworths, 1994 at p190.



- risks to the donor of restricted physical capacity for a short period after removal, possibility of septicaemia at the woundsite etc.; *and*
- significant other risks to the donor and/or recipient particular to the type of organ or tissue being removed and particularities on the participants (e.g. poor health condition).

Lord Templeman felt that general dangers inherent in an operation did not have to be disclosed.<sup>99</sup> This is perhaps too restrictive a view in the context of LDT, one might, for instance, think it reasonable to require a practitioner to disclose the normal risk of death due to not coming out of the anaesthetic to the recipient and donor. Equally, it can be argued that Lord Bridge's view that substantial risks of grave adverse consequences (such as 10% chance of a stroke) must be disclosed is too restrictive in the LDT context; one might think that reasonable disclosure to the donor and recipient would include disclosure of those donation risks that were not substantial but significant and related to adverse consequences that were not grave but simply significant (e.g. risk of septicaemia to the donor's woundsite, which is usually less than a 5% risk, ought to be disclosed to donor and recipient, risk of donor serious injury and/or death in the more novel risky forms of living organ donation - i.e. lung lobe and pancreas vessel length donation - see 3.4.2.2.).

### Reasonable Patient Test.

A jurisdiction using a reasonable patient base test (e.g. New Zealand, South Africa) would probably require a higher standard of disclosure to a living organ donor and recipient. For instance, donors and recipients can reasonably be expected to require:

- treatment as an interdependent pair for the purposes of disclosure;
- disclosure of non-medical factors;
- disclosure of the risk of death or serious injury from organ donation in a wider range of cases than under the professional based standard (e.g. not just lung lobe

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<sup>99</sup>[1985] 1 All ER 643.



and pancreas vessel length donation but probably also even liver segment and kidney donation); *and*

- greater disclosure with regards to the prospective risks and consequences for the recipient.

This would be the case irrespective of the fact that one or more competent bodies of medical opinion would probably not be inclined (at least in a standard living kidney donation) to take all, or even necessarily any, of these factors into account (unless legally obliged to) in determining disclosure.

### Therapeutic Privilege.

The notion of therapeutic privilege is particularly in line with the idea that it is for the medical practitioner to determine what disclosure is reasonable in the circumstances (professional based test). However, even the notion that disclosure is based on the requirements of the reasonable patient might result in non-disclosure being accepted on therapeutic grounds, such as where relevant information would “harm an unusually nervous, disturbed or volatile patient.”<sup>100</sup>

While concealment offends the principle of self-determination and can actually compromise the independence of decision-making, it is basically accepted in circumstances where the non-disclosure at issue is considered beneficent. However, Skegg has pointed out that non-disclosure is less acceptable in non-therapeutic procedures. In the context of the professional-based disclosure test he concludes that even if there was an established practice of non-disclosure in non-therapeutic cases (which there is not),

"it is highly unlikely that judges would accept that evidence of such a practice conclusively established that a doctor was not in breach of the duty he owed to the patient" <sup>101</sup>

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<sup>100</sup>Rogers v Whittaker [1993] 4 Med LR 79 at 83.

<sup>101</sup>Skegg, *Law Ethics and Medicine*, Oxford University Press, 1984, 84.



Concealment in the area of living donation is hard to justify at all because donation is not even undertaken for the benefit of the donor it must be the product of the donor reaching an autonomous decision after being informed of all the significant factors involved it cannot be justified at all.<sup>102</sup> Edmund Davies LJ has even extra judicially stated that disclosure must take place where the donor does not wish it,

”however eager the donor is to play out his self sacrificial role, the surgeon is under a legal duty to make clear to him the risks involved. He may not want the truth, but in this case the truth must be forced upon him”<sup>103</sup>

Non-use of therapeutic privilege should also be extended to the recipient who being interdependent with the donor requires disclosure in all the significant areas in order to make a moral decision.

### Experimental Procedures

Whilst the law relating to experimental procedures is not highly evolved, there are some general points that can be taken into account.

- *Firstly*, whilst the law is not designed to discourage the use of experimental techniques or practices<sup>104</sup> a new experimental method must reasonably seem to be more likely to bring about the recovery of the patient than the old one.<sup>105</sup> In LDT this *appears* to mean that a new form of living organ donation must be a better option than it’s cadaveric counterpart in terms of prospective benefits and detriments. However, in reality the prospective waiting time for a CDT must also

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<sup>102</sup>This is why it is difficult to accept the use of incompetent donors at all, unless through psychological benefit (or the avoidance of psychological harm) that outweighs the detriment of extraction the procedure can be shown to be, in all probability in the incompetents best interests - see chapter 7 for a further discussion of this area.

<sup>103</sup>The Patients Right to Know the Truth, *Proc Roy Soc Med*, 1973, 533 at 535.

<sup>104</sup>Qidway v Brown [1984] 1 N.S.W.L.R 100 "every innovation has to be performed for a first time. That something has not been done before is not proof that it ought not be done." per Hurlley J.A.

<sup>105</sup>Civil Liability of Physicians for New Methods of Treatment and Experimentation: A Comparative Examination, *Med Law Review*, 1995 (Spring), 3, 22-52 at 29-30. The burden of proving a choice was the best practice lies with the defendant in many jurisdictions.- see, for example, Anderson v Chasney and Sisters of St Joseph [1949] 57 Man R 343; Crits v Slyvester [1956] O.R. 132 (Ont C.A. per Schroeder J.A. at 148); G.Memeteau, *Le Droit Medical*, Litec, 1985, 307-308



be factored into the equation - in some situations CDT may be superior to LDT in terms of an abstract comparison of the two but LDT may still be justified by reference to the fact that of a long expected waiting time or exceptional need to conduct a transplantation in the particular circumstances.

- *Secondly*, disclosure levels will also be affected by the extent of experimentality of a procedure. Some forms of living organ donation may be new but *historically conducted on a medically indicated basis* (e.g. donation of a lung lobe) the knowledge and experience of them in this context being taken into account in assessing their degree of experimentality.
- *Thirdly*, while disclosure should be high in the experimental situation, leeway should also be given for the considerable variances in approach that might exist (e.g. transplant practitioner have very variant attitudes towards transplant scenarios in general and in experimental situations.<sup>106</sup>
- *Fourthly*, in an experimental situation there ought to be an explanation of the possibility of unknown risks actualising (in both reception and donation in the case of LDT.<sup>107</sup> Interestingly this requirement is embodied in Colombia's transplant law which states that the donor and recipient must have been warned in advance of the impossibility of knowing with certainty all the risks that the procedure may entail, on account of the possibility of unforeseen situations.<sup>108</sup>

#### 5.3.2.2. Range and Depth of Disclosure to the Recipient

There is little discussion of the depth of disclosure to recipients under transplant legislation although Indian law requires the medical practitioner to explain all possible effects, complications and hazards; all presumably meaning all that are beyond the de minimus level. The range of disclosure can be limited to apparently more medical aspects, as is the case in Indian and Bolivian law.<sup>109</sup> Some laws are vague about the required level of disclosure, for instance, Argentinean law states that the recipient

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<sup>106</sup>This point is brought out in the discussion of professional attitudes toward living donor transplantation in chapter 10.

<sup>107</sup>Gieson, Civil Liability of Physicians for New Methods of Treatment and Experimentation: A Comparative Examination, *Med Law Review*, 1995 (Spring), 3, 22-52 at 35. Several authorities are presented for this view.

<sup>108</sup>Decree No. 1173 of 6 June 1989 at section 35.

<sup>109</sup>Decree No. 55, 1987, sections 9 and 10).



must be informed of the likely risks and benefits of the procedure.<sup>110</sup> Theoretically the term 'benefit' could include social, psychological and other benefits. Similarly, Panama's law requires that physicians who undertake a transplant inform the recipient of the consequences of the procedure as well as the risks.<sup>111</sup> It may be that information about consequences could extend beyond the purely medical aspects. Greek law is almost identical on this point in placing a duty on physicians responsible for the removal to provide the recipient with information relating to the possible consequences of the removal and transplant.<sup>112</sup> Some laws, e.g. Russian Federation<sup>113</sup> and Vietnam,<sup>114</sup> simply require the recipient to have given consent.

There are also some novel provisions in terms of the range of information that must be disclosed. Bolivian law is unusual in specifically stating that the recipient must be informed as to whether the organ came from a living person or a dead one. Importantly the recipient is also able to get information on the clinical value of the donation with the regulation stating that, "the recipient is also to be informed regarding the results of tissue compatibility tests between the organs or tissues of the donor and of the recipient as well as the potential immunological risks and reactions" (This information is to be provided in writing).

#### **5.3.2.3. Range and Depth of Disclosure to Donors.**

Most transplant legislation fails to explicitly state the depth of information that must be disclosed to the donor. A typical example is French law which states that the donor must be "informed in advance of the risks to which he is exposed and the possible consequences of removal."<sup>115</sup> One is left to interpret the depth of information that must be communicated; a practitioner cannot disclose all the risks and possible consequences so this provision may be construed as excluding de minimus risks or involving disclosure only of risks that are significant.

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<sup>110</sup>Transplantation Law No. 24193 of 24 March 1993 at section 13.

<sup>111</sup>Law No. 10 of 11 July 1983 Regulating the Transplantation of Organs and Anatomical Parts and Laying Down Other Provisions at section 6.

<sup>112</sup>Section 5-6 of Law No. 1383 of 2 August 1983.

<sup>113</sup>Law of 22 December 1992 at section 6.

<sup>114</sup>Law of 30 June 1989 On the Protection of Public Health at section 30(1) and 30(3)

<sup>115</sup>Law No. 94-654 of 29 July 1994 at Article L. 671-3.



Transplant laws also have considerable variations as to the range of information they require to be communicated to the donor. The implication within the French law is that disclosure is limited to more medical risks and aspects of the procedure and its consequences - an approach which is seen in many more jurisdictions including Algeria,<sup>116</sup> Belarus,<sup>117</sup> Bolivian law,<sup>118</sup> Bulgaria,<sup>119</sup> Canada (model law),<sup>120</sup> Cyprus,<sup>121</sup> Hungary,<sup>122</sup> Kuwait,<sup>123</sup> Mexico,<sup>124</sup> Northern Territory,<sup>125</sup> Poland,<sup>126</sup> Queensland,<sup>127</sup> Slovakia,<sup>128</sup> Slovenia,<sup>129</sup> Sri Lanka,<sup>130</sup> Sweden,<sup>131</sup> Tasmania<sup>132</sup> and Western Australia.<sup>133</sup>

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<sup>116</sup>This law states that the physician must inform the donor of any medical risks which the removal may entail for the consent to be valid (Law No. 85-05 of 16 February 1985 at section 162).

<sup>117</sup>See Article 3 of the Draft Law of the Republic of Belarus On the Donation and Transplantation of Human Organs and Tissues, 1995. There are also transplant provisions within general law.

<sup>118</sup>Provides for the donor to be given information concerning the health risks of the procedure (section 10 of Regulations on the Use of Organs and Tissues 15 March 1982).

<sup>119</sup>The 1996 law demands that the donor has been given a clear explanation of the risks involved in the removal prior to giving consent.

<sup>120</sup>Requires that the donor understands the nature and consequences of transplanting tissue from his or her body during his or her life (section 5(1) this applies to over 16 year olds. For provision relating to under 16's see chapter on capacity).

<sup>121</sup>The donor must be duly informed of the medical consequences of removal (section 7(3) of Law No. 97 of 1987).

<sup>122</sup>The physician performing the removal procedure is responsible for informing the donor in a thorough and detailed manner of the necessity for the operation, the risks it entails, and the sequelae which might occur subsequently (section 2(1) of Ordinance No.18 of 4 November 1972).

<sup>123</sup>Requires that the donor be given information in writing of the effects to his health that may result from the removal of a specific organ (Decree No. 55 of 20 December 1987 On Organ Transplantation at section 4).

<sup>124</sup>Provides that the donor must have been fully informed of the risks to himself of the operation and the consequences to himself of the removal of the organ, and the degree of probability of a successful transplant (Federal Regulations of 16 August 1976 On the Use of Human Organs, Tissues and Cadavers at section 29). It is somewhat uncertain whether or not this provision extends beyond more medical consequences / possible effects of removal.

<sup>125</sup>Law requires that the physician explain the nature and effect of the removal from the body of the tissue specified in the consent (Act No. 121 of 1979 the Human Tissue Transplant Act at section 10(b)).

<sup>126</sup>The donor must "be informed in detail about the intervention, the risk connected with it and any possible typical consequences for his health condition" (Law of October 26, 1995 at Article 9(1) point 5).

<sup>127</sup>This law simply requires that the donor is prepared to donate in the light of medical advice furnished him (The Transplantation and Anatomy Act 1979-1984 at section 10(c)).

<sup>128</sup>The living donor must be "fully informed of the risks entailed for his health" (Law of 24 August 1994 at section 46(3)).

<sup>129</sup>The donor must have formed a consent that reflects his / her true will and based on an "appropriate explanation about the nature, purpose and course of the operation, probability of its success and usual risks" (The Law of The Transplantation of Human Body Parts For the Sake of Medical Treatment 1996 at Article 10).

<sup>130</sup>Requires that the nature and effect of donation be explained prior to consent being given (The Transplantation of Human Tissues Act, No. 48 of 1987 at section 8(3)).

<sup>131</sup>Law No. 831 of 8 June 1995 at section 10 states that the donor is to be informed of the nature of intervention and the risks entailed (*IDHL*, 1996, 47(1), 28-30 at 29).

<sup>132</sup>The Human Tissue Act 1985 at section 9(b) - requires that the physician explain the nature and effect of the removal from the body of the tissue specified in the consent

<sup>133</sup>Act No. 116 of 1982 at section 8(1)(c). Provision as above.



Of course when a regulation specifies disclosure of consequences it could expand beyond medical factors to include social, familial and other consequences. Even when the regulation merely specifies disclosure of 'medical aspects' the term medical may well include psychological - psychological risks are very much within the normal ambit of disclosure - it could be added that psychological benefits are as well in the case of living donation. Some jurisdictions have recognised the unique position of the donor by explicitly requiring a *range* of factors to be disclosed; such as physical, psychological, mental, family, medical and social consequences. The Third Conference of European Health Ministers in Paris (16-17 November 1987) speaks of the donor being given "appropriate information before the removal about its possible consequences, in particular the medical, social and psychological effects, as well as about the implications of the donation for the recipient."<sup>134</sup> Spanish law states that the living donor must have been informed about the foreseeable physical, mental and psychological consequences of donation and the possible effects of the donation on the donor's personal, family and professional life as well as the benefits which it is hoped the recipient will derive from the transplant.<sup>135</sup> Romania,<sup>136</sup> Belgium,<sup>137</sup> Turkey,<sup>138</sup> Tunisia<sup>139</sup> and Colombia<sup>140</sup> have similar provisions. Turkey has a unique addition in also requiring the donor's spouse to also be informed.<sup>141</sup> The recent Netherlands law states that disclosure must include information on, "the nature and

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<sup>134</sup>Adopted as para 11. of The Council of Europe Recommendation No.R (79) of The Committee of Ministers to the Member States. Reprinted in the World Health Organization's Book, 'Legislative Responses To Organ Transplantation,' *Martinus Nijhoff*, 1994, Appendix 1.

<sup>135</sup>This information should be provided by the physician who is to carry out the removal procedure according to 1979 law (No. 30 of 1979 at section 4) but the 1980 Crown Decree (No. 426 of 22 February 1980 at section 3) supersedes and apparently overrules this in stating that a physician other than the one responsible for the removal shall provide this information and check the donors competence.

<sup>136</sup>This law states that the donor can only give consent after being "fully informed by the doctors about the possible physical, psychical, family and professional risks and consequences following the act of harvesting" (Law of 1996 at Article 4(2)).

<sup>137</sup>The physician who is to carry out the removal must provide clear and complete information to the donor and any person whose consent is required on the physical, mental, family, and social effects of the removal procedure (Law No.32 of 1986 at section 9).

<sup>138</sup>Turkish law requires physicians to, "inform the donor of the possible risks entailed by the removal procedure and its medical, psychological, family and social consequences." The donor must be informed of the benefits to the recipient (Law No. 2238 of 29 May 1979 at section 7(a)).

<sup>139</sup>The law requires the donor to be informed of the possible consequences of his decision by the chief physician of the hospital department in which the organ is to be removed. The information is to include all the foreseeable physical and mental consequences of organ removal, and the possible repercussions of removal on the donor's personal family and professional life and all the results that the recipient can anticipate as a result of the transplantation (Law No. 91-22 of 25 March 1991 at section 7).

<sup>140</sup>This law requires that the donor be given, "prior information on the consequences of his decision to the extent they are foreseeable from the somatic, mental and psychological standpoint, and on the possible repercussions that the donation may have for his personal, family and professional life, as well as on the anticipated benefits of the transplantation for the recipient" (Decree No.1172 of 6 June 1989 at section 35).

<sup>141</sup>Law No. 2238 of 29 May 1979 at section 7.



object of the removal, and also the foreseeable risks for his health and the conditions affecting his life.”<sup>142</sup> The Netherlands transplant law is unique in expressly stating that the donor must be given information on the provisions of the law itself concerning the reimbursement of expenses.<sup>143</sup> It also has a very modern and thoughtful feature of requiring different formats for the presentation of information; information must be presented “orally and in writing and, where appropriate, with the aid of audiovisual means.” This approach will particularly aid persons with certain types of disability (e.g. reading, hearing difficulties).

Several jurisdictions do not set out a list of consequences and possible effects the donor must be informed of, but are nevertheless broadly framed. For instance, in Finland, a physician, not being the physician who is caring for the recipient, shall explain to the donor what is entailed by the procedure and its effects for the donor himself and for the recipient.<sup>144</sup>

### **5.3.3. The Requirement for Donor and Recipient Informed Understanding of Disclosure.**

Competent donors and recipients would be able to bring an action using the tort of battery on grounds that the consent was unreal if it were given without understanding of the basic nature of the procedure and its purpose. However, in terms of independent autonomous decision making understanding of all the significant aspects of LDT is important. A reasonable donor or recipient might expect a practitioner to make reasonable attempts (e.g. through informal interviewing) to ensure that (s)he understands the central risks, benefits and other significant aspects of the procedure. A reasonable attempt would include making reasonable efforts to ensure the approach to communicating the significant aspects is one which is acceptable for the particular donor and recipient (e.g. taking into account general intellectual capabilities, language, disabilities and special learning needs). Under a professional standard a

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<sup>142</sup>Ibid.

<sup>143</sup>Law of 1996, section 3(2).

<sup>144</sup>A statement must be included in the application to the National Board of Health that this information has been given to the donor (Law No.355 of 26 April 1985 at section 2 - see also Ordinance No. 724 of 23 August 1985 On the Removal of Human Organs and Tissues for Medical Purposes). Under GDR law the donor must, prior to giving consent to the removal, have been informed of the possible consequences of and risks associated with the removal and of all available after-care facilities. Under Greek law the physicians responsible for any removal or transplantation procedure have a duty to provide the potential donor with information relating to the possible consequences of the removal and transplant, and the responsible physicians at the transplantation unit must verify that these conditions have been met as regards the giving of voluntary consent, correct form etc. (section 5-6 of Law No.1383 of 2 August 1983).



competent body of medical opinion could be brought forward that would only make minimal attempts to ensure the above standards of communication. The amplified need for understanding in LDT might mean that a court would reject such a competent body of medical opinion in favour of an approach ensuring more substantial quality in communication. The way around the uncertainty of how general principles would be applied in this area is, of course, for legislation or regulations to specify exactly what factors must be disclosed to the donor and recipient and how far the practitioner must go in ensuring such information is understood. Legislation could also address the problem that donors and recipients might not understand all the relevant factors, despite the practitioners best attempts, by requiring psychological evaluation of donors and recipients. Donors and recipients could be required to write (or otherwise evidence) a short statement on the reasons why they want to go ahead with an LDT. From this statement a more objective judgment could be formed about the appropriate way forward; from rejecting the transplantation, to offering further clarification/information or making further checks to going ahead as is.

#### **5.3.3.1. The Recipient.**

Portugal<sup>145</sup> and Hong Kong (for donations which are *not* between genetic relatives or spouses of 3 or more years standing<sup>146</sup>) are the only provisions which require actual understanding by the recipient of information communicated.

#### **5.3.3.2. The Donor.**

Interestingly The Council of Europe in its recent Draft Protocol on Organ Transplantation states that LDT may only be conducted where donor consent is informed.<sup>147</sup> Although it does not define what informed means, such a requirement would probably generate a duty on the practitioner to ensure the donor understands the significant aspects of the process of LDT.

8 *European laws* (Denmark,<sup>148</sup> Sweden,<sup>149</sup> Norway,<sup>150</sup> Portugal,<sup>151</sup> The Netherlands law,<sup>152</sup> Russian Federation,<sup>153</sup> Slovenia<sup>154</sup> and the UK under the Human Organ

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<sup>145</sup>Law No. 12 of 22 April 1993 at sections 7 and 8(1).

<sup>146</sup>Section 5(4)c of Ordinance No. 16 of 1995.

<sup>147</sup>Steering Committee on Bioethics (CDBI) (97)5, Article 7.

<sup>148</sup>Section 13(3) of Law No. 402 of 13 June 1990 On the Examination of Cadavers, Autopsies and Transplantation.



Transplants Act 1989 for transplants defined under the Act as between person who are not genetically related<sup>155</sup>) and 3 *non-European laws* (Hong Kong,<sup>156</sup> Lebanon,<sup>157</sup> and South Australia<sup>158</sup>) impose some requirement on the practitioner to ensure donor understanding. Exactly what must be disclosed and what must be understood varies. Most jurisdictions appear to limit practitioner to ensuring donor understanding of clinical, perhaps including psychological, aspects of donation. For instance, Australian law merely requires the practitioner to ensure the donor has understood, in the light of medical evidence furnished him, "the nature and effect of the removal and the nature of the transplantation"<sup>159</sup> and Danish law, merely requires the physician to ensure donor understanding of disclosure of the nature of the procedure, its consequences, and the risks.<sup>160</sup> It is of course possible, but by no means certain, that non-clinical (e.g. social, economic) as well as clinical consequences would need disclosure. Portugal's law is very specific and potentially quite protective of the donor in requiring donor consent to be informed,<sup>161</sup> with the physician having to inform the donor,

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<sup>149</sup>This law declares that the decision whether the removal shall take place shall be made by the chief physician or the assistant chief physician at the hospital (not being the physician in charge of the care of the recipient patient) who must also inform the donor of the nature of the operation and the risks inherent in it. The physician to whom the consent is given must satisfy himself that the donor has understood the significance of the information given (section 3 and 5 of The Transplantation Law (No. 190) of 15 May 1975).

<sup>150</sup>This law requires that before giving his consent the donor must have been provided by a physician with information on the nature of the operation and its possible consequences. This physician has an obligation to ensure that the donor has understood the information provided to him and its significance (section 1 of Law No. 6 of 9 February 1973).

<sup>151</sup>Law No. 12 of 22 April 1993 at section 7 and section 8(1).

<sup>152</sup>Law of 24 May 1996 (see *IDHL*, 1996, 47(4), 469-475) coming into force in January or February 1998 requires the person removing the organ shall ensure that the donor has given consent with full knowledge of the consequences (section 3(2)).

<sup>153</sup>The donor must have been warned of any complications that could affect his health and must have given informed consent.

<sup>154</sup>Requires that the donation be an expression of the donor's free will a - Article 10 of 1996 Law.

<sup>155</sup>These must be authorised by ULTRA who must be satisfied amongst other thing that the donor was given an explanation by a registered medical practitioner of the nature of the medical procedure for, and the risk involved in, the removal of the organ in question and understands the nature of the medical procedure and it's risks, as explained by the practitioner, and consents to the removal in question. UK and Hong Kong law are similar in respect of their limited field of application (i.e. do not apply to genetically related donors which are the most common by far).

<sup>156</sup>The committee authorising donations which are *not* between genetic relatives or spouses of 3 or more years standing must be satisfied that that the donor understands the nature and consequences of the removal (section 5(4)c of Ordinance No. 16 of 1995).

<sup>157</sup>The physician must inform the donor of the consequences and risks of the intervention and satisfy himself that the donor has properly understood (Decree No. 109 of 16 September 1983 On the Removal of Human Tissues and Organs for Therapeutic and Scientific Purposes at section 1(2)).

<sup>158</sup>Section 9(2) of the Transplantation and Anatomy Act 1983).

<sup>159</sup>Section 9(2) of the Transplantation and Anatomy Act 1983).

<sup>160</sup>Section 13(3) of Law No. 402 of 13 June 1990 On the Examination of Cadavers, Autopsies and Transplantation.

<sup>161</sup>Law No. 12 of 22 April 1993 at section 8(1).



"in an honest, appropriate, and comprehensible manner of the possible risks, the consequences of donation and treatment, and any untoward effects, as well as the precautions to be observed subsequently."<sup>162</sup>

Slovenian law simply requires that the donation be based on the appropriate information - a provision that would probably mean that the practitioners, before going ahead with removal, would have to ensure that the decision itself is based on understanding of the significant factors.

With respect to disclosure pre-requisites, UK transplant legislation only regulates the position of donors that are defined as non-genetically related to the recipient under the HOTA.<sup>163</sup> This regulation occurs in the The Human Organ Transplants (Unrelated Persons) Regulations.<sup>164</sup> Regulation 3(2)b requires that the donor consents, Regulation 3(2)e adding that the donor and recipient must both have been interviewed by a person who appears to the ULTRA to have been suitably qualified to conduct such interviews. This person then reports to the Authority that certain conditions are satisfied and refers to any difficulties of communication experienced and how these difficulties were overcome.<sup>165</sup> One of factors ULTRA must be satisfied of<sup>166</sup> is that a registered medical practitioner has given the donor an explanation of the nature of the medical procedure for, and the risk involved in, the removal of the organ in question.<sup>167</sup> Additionally the authority must be satisfied that the donor *understands* the nature of the *medical procedure and the risks* as explained by the registered medical practitioner, and consents to the removal of the organ in question.<sup>168</sup> Presumably if ULTRA allowed or disallowed a donation its decision could be subject to an action for judicial review for incorrect application of the regulations. However, section 2(3) of HOTA only requires that the Authority is *subjectively* satisfied that the requirements under the regulations have been met. Proving that the Authority was not satisfied would require *very strong objective evidence* that the Authority couldn't

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<sup>162</sup>Law No. 12 of 22 April 1993 at section 7.

<sup>163</sup>Including distant relatives, spouses and persons who are only related emotionally (section 2 of HOTA - discussed further in chapter 6C(i)b).

<sup>164</sup>1989 (SI No. 2480 passed by the Secretary of State pursuant to section 2(3) of HOTA).

<sup>165</sup>The Human Organ Transplants (Unrelated Persons) Regulations 1989 (SI No. 2480). Regulation 3(2)e.

<sup>166</sup>Regulation 3(1)c *ibid.* An exception is donations that are subsidiary to medical treatment (e.g. therapeutically necessary heart or cornea removal).

<sup>167</sup>Regulation 3(2)a *ibid.*

<sup>168</sup>Regulation 3(2)b *ibid.*



have been satisfied. Interestingly Italian law mitigates against the requirement for informed understanding, and perhaps reflects different cultural priorities, in requiring donation to occur spontaneously!!<sup>169</sup>

## **5.4. Conclusions.**

Tom Beauchamp has summarised the problems with professional based disclosure standards in the context of the US,

"We have a strong tendency in the United States to look to legal and regulatory approaches to informed consent for the relevant standards, but it has become progressively clear that the focus of statutory law, case law and regulatory guideline has been on disclosure and that this focus is misguided. Problems about the quality and adequacy of consent probably cannot be resolved unless conventional disclosure requirements are abandoned and a shift occurs toward quality of understanding in the subject, patient and representative. From this perspective, the central problems about informed consent are issues of communication rather than the abstract and disembodied issues about proper legal standards of disclosure that have so long dominated the subject literature."<sup>170</sup>

The central philosophy behind this limited approach to disclosure is the notion that medicine is generally beneficent and practitioners require protection from a floodgate of litigation. The problem with this reasoning is that even if it were accepted that allopathic medicine is generally beneficent<sup>171</sup> liability for insufficient disclosure and communication can clearly *benefit* medicine by providing an impetus for practitioners to fully respect and support patients to make informed, autonomous decisions. The need for prospective organ donors and recipients to make such decisions is particularly high and demands special attention. Extensive liability is only likely to generate defensive medicine in cases of technical competence.

Currently there are variant legal standards of disclosure both within and between general principles of law and transplant legislation. Approaches range from those emphasising the professional based test or disclosure limited to medical aspects of the procedure *to* those emphasising the actual needs of the reasonable patient, extensive

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<sup>169</sup>Law No. 458 of 26 June 1967 applying only to kidney donation.

<sup>170</sup>A Patients Right to Know, at chapter 7.

<sup>171</sup>A contrasting view is that conventional medicine *generally* is inadequate and a holistic approach more appropriate for human growth - a point briefly raised at the end of the PhD introduction.



disclosure and understanding of what is disclosed.

There is no rational basis for maintaining differences in disclosure and communication requirements between jurisdictions; the need for donor and recipient to receive a high level of disclosure and understand the significance of information disclosed is a matter of universal principle not cultural relativity. In the case of organ LDT the way forward is clear; international co-operation to achieve comprehensive harmonised standards set out under transplant legislation. Whilst it may not be possible for transplant legislation to lay out each thing that must be disclosed within each form of organ donation, it could clearly state the general principles and allow for statutory guidance to practitioners to lay out specific disclosures that would need to occur to meet the required standards.

In terms of its general approach, transplant legislation should emphasise the need for practitioner to make reasonable attempts to ensure donor and recipient understanding of a wide breadth and depth of information and make this information available in a variety of formats. In terms of breadth there must be an emphasis on reasonable disclosure of relevant non-clinical factors including disclosure of the fact that economic factors (like potential loss of earnings and expenses related to taking time off work to donate) can be of serious material bearing to decision-making for the donor and potentially the recipient. Economic factors<sup>172</sup> could come within disclosure of social consequences and/or 'consequences for family / professional life' but given that this is not certain they warrant inclusion as a separate category of information that should be disclosed.

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<sup>172</sup>See chapter 8 for further detail.



## **Chapter 6 Voluntariness in LDT.**

### **6.1. Introduction**

Whilst law has traditionally not inquired as to the motivation or rationality of decisions made by competent persons it has been prepared to intervene in some cases where a decision is not made in accordance with its maker's true will through *external* influences. This question of voluntariness is particularly critical in LDT; the whole purpose of which is compromised by 'false' decision-making by the prospective donor or recipient. At the same time it is possible to hypothesise that the prospective donor, as a potential 'saviour,' is particularly vulnerable to external pressures and influences ranging from the gentle to the outright coercive. Consequently, it is not surprising that transplant legislation usually gives special attention to the direct question of voluntariness in living donation. Additionally voluntariness is covered indirectly where permissible forms of donation in terms of donor-recipient relationship and limitations, related to institutional or other status, on who can be a donor or on what basis are specified. General principles of law relating to voluntariness retain an important role, not just for the recipient but for 'fleshing out' the meaning of voluntariness.

### **6.2. Voluntariness and LDT in Practice**

While little data exists on recipient motivations for accepting LDT, a considerable amount examines donor motivation in gifting. A minority of people who having decided to donate have ambivalent motivation. In one study Simmons et al., found that 12% of donors would be relieved if they were not able to donate and a further 1% would be very relieved.<sup>1</sup> This 13% of donors aware that they were acting out the desire to donate may be the 'tip of an iceberg' of donors who consciously or unconsciously do not want to donate or have denied or rationalised away ambivalence.<sup>2</sup> Fellner and Marshall

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<sup>1</sup>Gift of Life ibid at 149-197 particularly 154-155.

<sup>2</sup>21% of donors who, pre-transplant, agreed a little with the statement "I sometimes feel unsure about donating." A further 5% agreed with this statement a lot (ibid 149-197 particularly 154-155). A larger percentage of donors in this study did admit to fears surrounding donation. 20% of donors agreed a lot that surgery frightens them and a further 31% agreed a little. One third of donors were concerned about



have pointed to some cases where immediate decision-making was the unconscious product of donors wanting to avoid inner conflict in making the decision<sup>3</sup> and cases where prospective donors passively let the selection process decide for them<sup>4</sup> - this being reflected in one study by 5% of donors never making a conscious choice about whether to donate or not but simply taking a succession of steps locking them into the process of donation.<sup>5</sup> We have also seen in chapter 3.4.2.4. that a minority of between 3-8% of donors regret their decision post donation. Where a 'false' decision is made, as is no doubt the case in some of the above instances, it could be due to unconscious issues within the donor. These could include the compulsive need to donate to avoid intense guilt or self-criticism (which 46% of the public anticipated that they would feel if they were asked to donate but refused<sup>6</sup>) or gain absolution (one study found that a quarter of donors agreed with the statement that donation was one way to 'make up for the wrongs we may have done to others in our lives'<sup>7</sup>). Some people, having decided whether or not to donate, use unconscious mechanisms to reify their decision and insulate themselves from information that might challenge it.<sup>8</sup> Unresolved unconscious issues can lead to 'false' decisions both on their own and by the addition of external pressure to decide one way or another. The difficulty come in deciding when the law should step in to 'protect' prospective donors and what mechanisms, if any, can reliably be used to scrutinise and determine motivations before donation takes place

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their future with only one kidney and between 10 and 20% of donors were concerned about the length of their recovery period, the timing of the operation, the financial sacrifice involved and conflicts between their obligation to their immediate family and to the recipient. The level of stress in ambivalent donors was "extreme" according to the authors.

<sup>3</sup>Twelve Kidney Donors, *J Am Med Assoc*, 1968, 206, 2703-2707 at 2706.

<sup>4</sup>Twelve Kidney Donors, *J Am Med Assoc*, 1968, 206, 2703-2707 at 2706.

<sup>5</sup>R.G.Simmons et al., (Minnesota study) Gift of Life, *Transaction Books*, 1987 at 245.

<sup>6</sup>Written questionnaire completed by 116 adults in a Midwestern US City concerning attitudes to donation - findings presented in C.H.Fellner and S.H.Schwartz, Altruism in Disrepute: Medical Versus Public Attitudes Toward The Living Organ Donor, *The New Eng J Med*, 1971 (March 18), 582-585 at 584.

<sup>7</sup>29% of donors in the Minnesota study of 114 donors agreed that they 'had done something major in their life that their family did not approve of.' 20% reported that there was a period in their life when they and the recipient did not get along well. Ibid at p162.

<sup>8</sup>Kidney Donors, in J.Macauley and L.Berkowitz (eds.), Altruism and Helping Behaviour, *Academic Press*, 1970, 279.



The situational context within which donation takes place can of itself generate pressure. Firstly, the very fact of the prospective donor being asked to donate, or informed of the possibility, is borne out of a hope that this person will want to donate and this invites the prospective donor to at least consider the matter seriously when in some cases (s)he may have felt more comfortable avoiding it. Some prospective donors feel that the situation in itself leaves them with no choice but to offer. It could be suggested that philosophically a decision is involuntary where the prospective donor has been asked to donate - for example, the donor in interview 13 of the Norwegian interviews<sup>9</sup> basically explained that he *had* to donate because it was his duty. However, this extreme position would rightly not be adopted in law. Ethically a proactive as well as a reactive approach to prospective donors seems acceptable<sup>10</sup> provided there is an overarching context of an attempt to facilitate true will donor (and indeed recipient) decision-making and ensure motivation is acceptable.

Reducing, balancing or removing structural and attitudinal biases in favour of transplantation during the process is by no means easy. It has been pointed out that the very manner, "in which the donor is informed of the need for a related donor may make it difficult for him to resist volunteering."<sup>11</sup> There are also many aspects of the LDT situation that lend themselves to pressures being placed on people to donate.<sup>12</sup> General psychological literature suggests that the induced action-taking normally involved in being tested as a potential donor may produce compliance.<sup>13</sup> The more preliminary

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<sup>9</sup>See chapter 9.3.3.

<sup>10</sup>Westlie et al.'s study found 43.9% of donors had been asked by the family physician to donate and 40.6% had donated without being asked, while 10.3% had been asked by the family physician and 3.8% by a family member (L. Westlie, P. Fauchald et al., *Quality of Life in Norwegian Kidney Donors*, *Nephrol Dial Transplant*, 1993, 8, 1146-1150 and conversation with the main author of this study, Dr Lars Westlie, in Fredrikstad, Norway). The BTS 1995 Working Party Report found roughly equal use of a proactive and reactive approach to prospective living donors by transplant centres in the UK - see chapter 9.3. for further discussion.

<sup>11</sup>Simmons et al., *Gift of Life*, *Wiley and Sons*, 1977, 159.

<sup>12</sup>Saks, *Social Psychological Contributions to a Legislative Sub Committee on Organ and Tissue Transplants*, *American Psychologist*, 1978 (July), 680-690.

<sup>13</sup>E.g. the induced actions of going for a blood test, checking for compatibility etc. sets the potential donor on a path from which it is a short step to compliance with eventual donation (see J.L. Freedman and S.C. Fraser, *Compliance Without Pressure: The Foot in The Door Technique*, *J of Personality and Soc Psych*, 1966, 4, 195-202.



behaviours induced (e.g. blood sample, tissue sample etc.) the greater the probability that the person will perform the target behaviour.<sup>14</sup> Schwartz's study of potential bone marrow donors found evidence that action taking was induced.<sup>15</sup> He noted how the 'Foot in the Door' technique could be successfully used in gaining the consent of donors; commitment (and difficulty of withdrawal) being increased through a series of small acts of compliance, such as taking blood tests etc.<sup>16</sup> Another psychological feature relevant to the LDT situation is that unanimity of viewpoint creates pressure to conform. In LDT hospital contact and information giving to the donor typically involves experts all essentially advocating transplantation<sup>17</sup> and the family will probably also be in favour of transplantation. Modelling<sup>18</sup> and social comparison<sup>19</sup> act as reinforcements when prospective donors and their families are invited to speak with past donors and their families. The prospective donor is being asked to make a big sacrifice but the need to pass tests helps to redefine the situation as one where the donor is lucky to have the opportunity to donate. Tests add credibility to the views of the physicians, helping to obfuscate any ambivalence the potential donor is experiencing.<sup>20</sup> As we have seen in the last chapter, prospective donors tend to rely heavily on medical professionals for information and advice sources in general. This reliance can be increased after the initial steps as noted in the Minnesota study of Simmons *et al.*, which found that,

"after the blood test most donors directed their information seeking toward the transplant physicians rather than towards an outside source."<sup>21</sup>

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<sup>14</sup>A. Bandura, *Principles of Behaviour Modification*, Holt, Reinhart and Winston, 1969.

<sup>15</sup>S.H. Schwartz, Elicitation of Moral obligation and Self sacrificing Behaviour: An Experimental Study of Volunteering to Be a Bone Marrow Donor. *J of Personality and Soc Psych*, 1970, 15, 283-293.

<sup>16</sup>Elicitation of Moral Obligation and Self-Sacrificing Behaviour: An Experimental Study of Volunteering to Be a Bone Marrow Donor, *J Pers & Soc Psych*, 1970, 15(4), 283-293. The foot in the door technique is a traditional sales technique.

<sup>17</sup>For this effect of expert power generally see J.R.P. French and B. Raven, The Bases of Social power (In D. Cartwright and A. Zander (Eds.), *Group Dynamics*, Harper and Row, 1968). For this impact of unanimity on decision making in general see S.E. Asch, Effects of Group Pressure Upon The Modification and Distortion of Judgements (In H. Guetzkow (Ed) *Groups, Leadership and Men*, Carnegie Press, 1951).

<sup>18</sup>Bandura, *Principles of Behaviour Modification* *ibid.*

<sup>19</sup>L. Festinger, A Theory of Social Comparison Progress, *Human Relations*, 1954, 2, 117-140.

<sup>20</sup>D.J. Bem, Self Perception: An Alternative Interpretation of Cognitive Dissonance Phenomena, *Psychological Review*, 1974, 81, 506-520.

<sup>21</sup>Gift of Life, *Wiley and Sons*, 1977 at 257.



The significance of this is that it can influence the prospective donor towards whatever outcome practitioners desire; as one donor commented the further he went into the process the more difficult it became to withdraw because of the building expectations of others around him.<sup>22</sup>

Recipients can also be influenced by many of the above factors - for instance the 'Foot in the Door Technique' would be relevant to prospective recipients where they have not already made up their mind whether or not to accept LDT as would modelling<sup>23</sup> and social comparison<sup>24</sup> where undecided prospective recipients are invited to speak with past recipients to encourage reception. Of course modelling and social comparison could work in the reverse direction were the prospective recipient within the context of a dialysis unit where dialysis was viewed as a preferred approach - e.g. because of an economic disincentive of the dialysis centre to refer patients for transplantation. The process of information giving will also exert an influence on whether the prospective recipient chooses LDT or not - for instance the way risks are evaluated and expressed by medical practitioners.

Beyond situational pressures there can be more unconscious or deliberate manipulation of the donor. In the context of US practice Saks has worryingly suggested that,

"some features of the process used by physicians to obtain informed consent from patients bear a troubling resemblance to the procedures used by police to obtain confessions from suspects: demand characteristics of the situation, perceptual and judgmental distortions, social relations distortions, and semantic and verbal distortions."<sup>25</sup>

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<sup>22</sup>Gift of Life at p260.

<sup>23</sup>Bandura, *Principles of Behaviour Modification* *ibid*.

<sup>24</sup>L.Festinger, A Theory of Social Comparison Progress, *Human Relations*, 1954, 2, 117-140.

<sup>25</sup>Social Psychological Contributions to a Legislative Subcommittee on Organ and Tissue Transplants *ibid* at 685.



A significant minority of donations involve direct pressure being applied on the donor according to studies so far. Simmons *et al.* noted overt pressure in 11% of cases<sup>26</sup> while Westlie *et al.*'s study of Quality of Life in Norwegian donors<sup>27</sup> indicates that 15.7% of donors experienced pressure in the process, 9.3% of this being to donate and 6.4% not to donate. The sources of this pressure were friends, family and medical personnel. As only 4.9% of donors experienced family conflict over the donation it may be that pressure was exerted as much, or more so, by friends and medical personnel as the family itself.

Direct pressure in it's mildest form would be 'persuasion'<sup>28</sup> other forms include subtle<sup>29</sup> and overt manipulation, coercion and the use or threat of results adverse to the decision-maker. Levels of pressures are difficult to quantify because of their very nature as somewhat hidden. This hiddenness inevitably also makes them difficult to remove; Simmons *et al.* have suggested that more subtle pressures appear inevitable.<sup>30</sup> Levels of pressure identified within the donor and recipient questionnaires conducted for this Phd, were extremely low (see 9.3.3.5 - page 296) and more commonly not to donate than donate. However, this study did not use any sophisticated methods to evaluate the true extent of pressure. There is a need in future European studies for a family systems based analysis of pressure in relation to donation with the tracking and uncovering of medical and family actions and motivations before, during and after the act of donation. One unique aspect of the EUROTOLD donor-recipient questionnaires was the presentation of data relating to pressure on recipients. A small number of recipients in the study stated that they experienced pressure this typically being to *not* receive. In

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<sup>26</sup>Gift of Life, Wiley and Sons, 1977, 158. Most of the donors who were openly pressured were ambivalent about donation-see next section.

<sup>27</sup>*Nephrol Dial Trans*, 1993, 8, 1146-1150.

<sup>28</sup>See Re T.

<sup>29</sup>For further discussion of this area see also W.Gaylin, On the Borders of Persuasion: A Psychoanalytic Look at Coercion, *Psychiatry*, 1974, 37(Feb), 1-9; T.Talseth et. al., Long-Term Blood Pressure and Renal Function in Kidney Donors, *Kidney International*, 1986, 29, 1072-1076; R.Cialdini et. al., Low Ball Procedure For Producing Compliance: Commitment then Cost, *Journal of Personality and Social Psychology*, 1978, 36(5), 463-476; R.D.Foss, Blood Donation and the Foot-In-The-Door Technique: A Limiting Case, *Journal of Personality and Social Psychology*, 1979, 37(4), 580-590; S.Schwartz, Elicitation of Moral Obligation and Self-Sacrificing Behaviour, *Journal of Personality and Social Psychology*, 1970, 15(4), 283-293; J.Freedman et. al., Compliance Without Pressure, *Journal of Personality and Social Psychology*, 7(2), 117-124.

<sup>30</sup>Gift of Life, Wiley and Sons, 1977, 431-3.



addition the study illustrates a number of ways that external influences can bear down on a recipient's decision - including the fact of who does and does not come forward as a potential donor, the basis for which is not always transparent.<sup>31</sup> As part of a family systems approach recipient motivation is worthy of further examination - the importance of the recipient making a choice that truly reflects his or her will should not be underestimated. One feature that may be frequently occurring is an assumption of the part of practitioners that dialysis and transplantation are the only viable options in the case of serious organ disease. This might result in pressure on patients to choose to merely await a transplantation (including perhaps a living donation) when they would prefer to explore naturopathic options for treatment.

Besides outright evidence that it exists an attempt to gauge the frequency and degree of pressure must also look at associated factors such as family conflict. Westlie *et al.*'s study indicated that 95.1% of donors said the donation had not led to any conflicts in relation to their family - the remainder saying it had led to 'some' conflict (3.7%) or 'severe' conflict (1.2%), this mainly being with a spouse. R.G.Simmons *et al.*, pointed to increased family cohesiveness consequent upon donation, although there was family conflict in 25% of cases as a consequence of the donor search. The authors suggest that these were families who were more likely to have had a history of significant family conflict.<sup>32</sup>

Another factor that could lend itself to pressure is donor-recipient dependency, but this has rarely been examined. Westlie *et al.*'s study found 68.3% of donors were able to categorically state there was no dependency between them and the donor.<sup>33</sup> Some of the remaining cases may have involved some dependency, which may have resulted in some decisions being partly based on donors feeling pressure inside of themselves to donate or from the recipient. However, dependency could have started post-donation in some instances.

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<sup>31</sup>See chapter 9.3.3.

<sup>32</sup>Ibid at 435.

<sup>33</sup>*Nephrol Dial Trans*, 1993, 8, 1146-1150.



## **6.3. Law and Voluntariness in LDT.**

### **6.3.1. General Issues.**

The main role of law of voluntariness in medical practice is to prevent medical treatment on a competent person that is not being voluntarily undertaken. This approach applies in all but the most exceptional situations.<sup>34</sup> In McFall v Shimp [1978] 10 Pa D&C (3d) 90 (Ct Comm Pl, Pa) the plaintiff, who had a rare bone marrow disease, brought an action seeking a direction that his adult cousin, the only suitable donor of bone marrow in the family, be required to submit to procedures for the extraction of bone marrow for transplantation into the plaintiff despite his unwillingness to do so. Justice Flaherty, in denying the plaintiffs claim, stated that,

"(f)or our law to compel the defendant to submit to an intrusion of his body would change every concept and principle upon which our society is founded. To do so would defeat the sanctity of the individual, and would impose a rule which would know no limits, and one could not imagine where the line would be drawn."

Medical professionals also have duties under general principles of law to ensure voluntariness. The knowingness of involuntariness would leave a practitioner open to being sued and/or criminally sanctioned for battery; and carelessness as to voluntariness resulting in damage would leave the practitioner open to being sued under the head of negligence - the minimum standards depending on the jurisdiction and the individual circumstances of the case.<sup>35</sup> Best practice with respect to donors would include proactive efforts by practitioners to ensure that: Giving is voluntary; the 'climate' for decision-making is as neutral as reasonably possible; *and* a process/system of moving toward decision making which affords the prospective donor good opportunities to

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<sup>34</sup>See e.g. Re S [1992] 4 All ER 671 where the High Court decided a woman should undergo a caesarian section despite her objection, to prevent the death of her unborn child.

<sup>35</sup>Standards which are discussed in chapter 5.



choose not to donate (e.g. by providing the donor with a way out without 'losing face'<sup>36</sup>) is devised. Practitioners would probably owe donor's a higher legal standard of care than the average recipient because the donor is more vulnerable to exploitation and is not undergoing the procedure for therapeutic benefit.

More contentious issues are raised by the setting aside of decisions held, in the presence of external pressure, to be against the true will of the decision-maker. Such a setting-aside occurred in the landmark English law case of Re T (adult: refusal of medical treatment)[1992] 4 All ER 649. Re T was a case where a mother who was a Jehovah's witness had, according to trial judge, influencing her daughter, who was not a Jehovah's Witness, to refuse a blood transfusion. The daughter was a patient who was admitted to hospital 34 weeks pregnant. Her condition worsened such that she was taken into intensive care. The Court of Appeal granted a declaration stating that in the circumstances it would not be unlawful for the hospital to administer a blood transfusion on the basis that the patient did not make a valid refusal to consent to this. Lord Donaldson MR stated that,

"it is wholly acceptable that the patient should have been persuaded by others of the merits of such a decision and have decided accordingly. It matters not how strong the persuasion was so long as it did not overbear the independence of the patient's decision. The real question in each such case is 'Does the patient really mean what he says or is he merely saying it for a quiet life, to satisfy someone else or because the advice and persuasion to which he has been subjected is such that he can no longer think and decide for himself?' In other words 'Is it a decision expressed in form only, not in reality?'"<sup>37</sup>

Lord Donaldson MR went on to say that two aspects can be of crucial importance in considering the effect of outside influences: *Firstly* the strength of will of the patient and

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<sup>36</sup>In Norway the Oslo centre avoids the donors losing face by simply telling the relatives that the medical conditions are not met.

<sup>37</sup>[1992] 4 All ER 649.



*secondly* the relationship of the 'persuader' to the patient. Butler Sloss LJ, concurring that undue influence had been brought to bear, suggested that,

"the degree of pressure to turn persuasion or appeals to affection into undue influence may... be very little."<sup>38</sup>

Stoughton LJ also concurred, although he made it very clear that in his view the decision was still voluntary, in the sense that it wasn't brought about by compulsion; however, it was invalid by reason of undue influence.<sup>39</sup>

Whilst one may debate the justifications of using voluntariness instead of undue influence, or vice versa<sup>40</sup> the key point of logic is expressed in Lord Donaldson's view that what matters is not how strong any persuasion is but whether that persuasion acted in such a way as to overbear the independence of the decision. What is controversial is that the decision was based on circumstantial evidence that the patient's true will was overborne by her mother; with no certainty that without the alleged external influence of her mother the patient would have decided against a blood transfusion (through internal confusion or genuine values). One might conclude that on the balance of probabilities there was pressure and she would have decided differently but should balance of probabilities be sufficient in such cases? Is there not a clear danger that judges will be more inclined to overturn those decisions by competent persons that fall outside their conception of what is rational with the attendant danger of infringement of the autonomy to think differently and, in the opposite direction, that decisions that fit the judicial conception of what is rational will be inadequately scrutinised. This is almost the intrinsic and unavoidable problem of the area of undue influence as a whole. Expectedly, *Re T* has not escaped the accusation that it is based on paternalistic considerations rather than protection of autonomy. As Kennedy and Grubb bluntly put it,

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<sup>38</sup>*Ibid.*

<sup>39</sup>*Ibid.*

<sup>40</sup>Traditionally undue influence is a doctrine used within a contractual context with voluntariness being more pertinent in the context of tort.



"perhaps the court adopted the undue influence approach out of it's desire that the patient should not die."<sup>41</sup>

Another possible example of notions of rationality, rather than simply questions of autonomy, being a factor in determining whether or not undue influence has occurred is the case of Poynter v Hillingdon Health Authority (23 April 1997 Unreported). In this case, the parents of a potential recipient of a cadaveric organ were clearly rejecting the allopathic model of treatment of organ disease. The plaintiffs claimed that the acceptance of the transplantation was the result of pressure, which one can imagine could take place in such a situation. The judge rejected the possibility of this without ever really examining it in detail possibly precisely because of a reluctance to pay proper attention to the significance of different concepts of best interests that are in opposition to medical model concepts of rationality. This type of situation could repeat itself in living organ donation - there might be a tendency amongst practitioners and even judges to overlook pressure on the donor and/or the recipient to go ahead with LDT. A consequence of *Re T* might be that a prospective recipients decision not to receive is overturned due to the determination that the decision has been reached because of external pressure. What would be almost inconceivable, however, is a prospective donor's decision not to donate being overturned because it was based on undue influence. This would set to dangerous a precedent, would damage the reputation of transplantation, would subject a person to a physically non-therapeutic procedure against their expressed will and would also be excluded under most jurisdictions simply because most transplant legislation requires express donor consent (e.g. Bolivia,<sup>42</sup> Peru<sup>43</sup> and Cuba<sup>44</sup>) or at least written consent.<sup>45</sup>

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<sup>41</sup>Medical Law: Text with Materials, *Butterworths*, 1994 at 238.

<sup>42</sup>Requires that the donor express consent without any reservations. Regulations On the Use of Organs and Tissues March 1982 at section 3(a).

<sup>43</sup>States that the donor's consent *and* the recipients acceptance must be free, conscious and express. Supreme Decree No. 014-88-SA of 19 May 1988 at section 15.

<sup>44</sup>Decree No. 139 of 4 February 1988 at section 80.

<sup>45</sup>Nearly all laws do - see chapter 4.5.



The evidence in these cases clearly needs careful examination and weighing by practitioners and, where cases come to court, judges. The dangers of utility and paternalism overriding autonomy should result in a strong reluctance to overturn the decision of a competent, most particularly so where evidence is circumstantial. People do have a general right to make decisions that are widely considered stupid or irrational and a high burden of proof that external pressure resulted in them making a decision they would not have otherwise made should be satisfied before their decision is overturned..

### **6.3.2. General Provisions Relating to Voluntariness in Transplant Legislation.**

Transplant laws typically have voluntariness requirements integral to the process of giving consent i.e. failure to meet them results in the consent being invalid, occasionally failure to meet requirements is a criminal offence.<sup>46</sup> Sometimes provisions merely reiterate what would be required under general principles of law (e.g. Algeria,<sup>47</sup> Bulgaria,<sup>48</sup> Cyprus,<sup>49</sup> Denmark,<sup>50</sup> Ecuador,<sup>51</sup> Kuwait,<sup>52</sup> Norway,<sup>53</sup> Panama,<sup>54</sup> Slovakia,<sup>55</sup> South Africa,<sup>56</sup> South Australia,<sup>57</sup> Vietnam,<sup>58</sup> Western Australia<sup>59</sup> and Zimbabwe<sup>60</sup> merely emphasise the need for consent within which the need for voluntariness is implicit). The laws of Finland<sup>61</sup> and Iraq<sup>62</sup> simply require that consent be given on a voluntary basis.

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<sup>46</sup>Law of 22 December 1993.

<sup>47</sup>Law No. 85-05 of 16 February 1985.

<sup>48</sup>Ordinance No. 15 of 30 April 1976.

<sup>49</sup>Law No. 97 of 1987.

<sup>50</sup>Law No. 402 of 13 June 1990.

<sup>51</sup>Law No. 64 of 26 May 1987 Reforming the Health Code.

<sup>52</sup>Decree-Law No. 55 of 20 December 1987 On Organ Transplantation.

<sup>53</sup>Law No. 6 of 9 February 1973.

<sup>54</sup>Law No. 10 of 11 July 1983.

<sup>55</sup>Law of 24 August 1994.

<sup>56</sup>Human Tissue Act, No. 65 of 1983.

<sup>57</sup>The Transplantation and Anatomy Act 1983

<sup>58</sup>Law of 30 June 1989 On the Protection of Public Health at section 30.

<sup>59</sup>Act No. 116 of 1982 To Make Provision For and in Relation to the Removal of Human Tissues for Transplantation, For Post-Mortem Examinations etc...

<sup>60</sup>Anatomical Donations and Post-Mortem Examinations Act No. 34 of 1976.

<sup>61</sup>Law No. 355 of 26 April 1985 at section 3.



In some jurisdictions general principles of law are needed to fill in the gaps left in transplant law. For instance, the model law of Canada (for non-regenerative tissue)<sup>63</sup> and the law of Venezuela<sup>64</sup> emphasise that consent to donation must be given without coercion - leaving the issue of whether donation in the face of coercion to donate or not donate would be acceptable if it still accorded with the decision-makers true will. The law of Argentina is clearer in simply emphasising that the decision must be of the donor's free will while simultaneously prohibiting coercion and inducement.<sup>65</sup> Slovenia<sup>66</sup> and Sweden<sup>67</sup> similarly stress that the donation must accord with donor's will. A variation of this approach is found in the Council of Europe's Resolution 78(29) Article 3<sup>68</sup> and its Draft Protocol on Organ Transplantation<sup>69</sup> which simply state that consent must be freely

Transplant laws of a number of jurisdictions (including those France,<sup>70</sup> Greece,<sup>71</sup> Northern Territory of Australia,<sup>72</sup> Poland,<sup>73</sup> Portugal,<sup>74</sup> Paraguay,<sup>75</sup> Sri Lanka,<sup>76</sup> Lebanon,<sup>77</sup> Syrian Arab Republic,<sup>78</sup> Queensland,<sup>79</sup> The Netherlands,<sup>80</sup> Tasmania,<sup>81</sup> and

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<sup>62</sup>Excepting the instance of persons who are killed by the state whose organs may be used regardless. Resolution No. 776 of 9 June 1981 of the Revolutionary Command Council Promulgating Law No. 60 of 1981 On Kidney Transplant Operations at section 1(a) and 1(b) respectively. This practice of using the organs of executed persons is also adopted in China and is of course more relevant to cadaveric donation.

<sup>63</sup>Uniform Human Tissue Donation Act 1990 at section 7(6).

<sup>64</sup>Law of 19 November 1992 On the Transplantation of Organs and Anatomical Materials in Human Beings at section 12.

<sup>65</sup>Law No. 24193 of 24 March 1993 On Transplantation of Organs and Anatomical Materials.

<sup>66</sup>Requires that the donation be an expression of the donor's free will - Article 10 of 1996 Law.

<sup>67</sup>States that the donation must not occur against the donors will. Law No. 190 of 15 May 1975 at section 4. This is the old law - translated copy of the new law is not yet available.

<sup>68</sup>On Harmonisation of Member States to Removal Grafting and Transplantation of Human Substances

<sup>69</sup>Steering Committee on Bioethics (CDBI) (97)5, Article 7.

<sup>70</sup>Law No. 76-1181 of 22 December 1976 at section 1. No comment is made on this point in the 1994 French law.

<sup>71</sup>Requires that the willingness to donate must be a freely declared one. Law No. 1383 of 2 August 1983 On the Removal and Transplantation of Human Tissues and Organs at section 5.

<sup>72</sup>Allows for certification by a medical practitioner that the consent was freely given which alongside other criteria constitute sufficient authority for the removal of the organ or tissue which, presumably in attempt to avoid pressure, can not be undertaken by the certifying practitioner. Law No. 121 of 1979 at section 10(iii).

<sup>73</sup>Law of 26 October 1995, Article 9(1) at point 7.

<sup>74</sup>Law No. 12 of 22 April 1993 at section 8(1).

<sup>75</sup>Law No. 836180 of 15 December 1980 at section 276.

<sup>76</sup>The Transplantation of Human Tissues Act, No. 48 of 1987 at sections 7 and 8.

<sup>77</sup>Decree No. 109 of 16 September 1983 at section 1(3).

<sup>78</sup>Law No. 31 of 23 August 1972 On the Removal and Transplantation of Human Organs From the Body at section 2(3).

<sup>79</sup>The Transplantation and Anatomy Act 1979-1984 at section 12(b)(iii).

<sup>80</sup>Law of 24 May 1996 section 3.



Tunisia<sup>82</sup>) also state this while in Belgium donation must occur freely and knowingly,<sup>83</sup> in Romania freely and in a deliberate manner<sup>84</sup> and in Colombia freely and voluntarily<sup>85</sup> with the intention of the donor overriding any contrary opinion of his relatives or any other person.<sup>86</sup> Cuban law states donation must be, "a free and expressly voluntary act of the donor or of his representative, performed for humanitarian reasons."<sup>87</sup> Turkish law, like Cuban law, includes a provision by which physicians are required to refuse any organ not given out of humane aspirations. Physicians are also required to refuse organs from persons unable to take their own decision for mental or psychological reasons; interpreted broadly this could include persons coerced or pressurised into donation.<sup>88</sup> Mexican law requires the donor to give his consent freely, without moral coercion, unambiguously and voluntarily!<sup>89</sup> The Council of Europe in its recent Draft Protocol on Organ Transplantation has latched onto this use of a variety of words in its statement that LDT may only be conducted where consent is informed, free, express and specific.<sup>90</sup>

It is surprising that the notion of 'true will being overborne' is not directly used within transplant legislation, particularly given that undue influence is specifically referred to within WHO Guiding Principle 3 (which states consent by the donor "should be free of any undue influence and pressure"<sup>91</sup>). Perhaps true will decision making is implicit in the idea of donation being free. The mention of pressure has often been more of a hindrance than a help; quite unrealistically (given pressures invariably exist) jurisdictions like Spain (the donation must be made freely, consciously and free of external pressure<sup>92</sup>) and Hungary (the removal must be consented to freely and in the absence of any

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<sup>81</sup>The Human Tissue Act 1985 at section 9(c)(iii).

<sup>82</sup>Law No. 91-22 of 25 March 1991 at section 2.

<sup>83</sup>Law of 13 June 1986 at section 8(1).

<sup>84</sup>Law of 1996 at Article 4(1).

<sup>85</sup>Decree No. 1172 of 6 June 1989 at section 32(c).

<sup>86</sup>Law No. 73 of 20 December 1988 at section 3.

<sup>87</sup>Decree No. 139 of 4 February 1988 at section 80.

<sup>88</sup>Law No. 2238 of 29 May 1979 at section 7.

<sup>89</sup>Federal Regulations of 16 August 1976 at section 24 and 26.

<sup>90</sup>Steering Committee on Bioethics (CDBI) (97)5, Article 7.

<sup>91</sup>Guiding Principle 3.

<sup>92</sup>Law No. 30 of 27 October 1979 at section 4(c).



pressure<sup>93</sup>) have required that agreement to donate is made *in the absence* of external pressure. It would surely be equally efficacious and more realistic just to exclude donations which evidence suggests are *the product* of inducement or coercion. The laws of the Russian Federation,<sup>94</sup> Belarus (draft),<sup>95</sup> Canada (model) for non-regenerative tissue)<sup>96</sup> and Venezuela<sup>97</sup> appear to do this but much will depend on interpretation in practice as to whether they are really excluding donations where there has been *any* coercion or simply those where evidence suggests the coercion has *overborne* the decision-makers true will. A clear example of the former approach would be Hong Kong whilst UK law is an example of the latter.

Hong Kong's Ordinance states that the Board authorising organ LDT's not legislatively defined as between genetic relative or spouses of 3 or more years standing<sup>98</sup> must be satisfied that donor consent was given *without* coercion or the offer of inducement<sup>99</sup> is overly restrictive. English law has similarly addressed coercion with specific types of donor - those *not* between persons defined as genetically related under the Act as part of regulation 3 of The Human Organ Transplants (Unrelated Persons) Regulations 1989 [SI No 2480] passed pursuant to HOTA 1989. The conditions include ULTRA being satisfied that removal was not *obtained* by coercion or the offer of an inducement (Regulation 3(2)c).<sup>100</sup> Regulation 3(2)e adds the requirement that the donor and recipient must have been interviewed by a person who appears to the Authority to have been suitably qualified to conduct such interviews and who has reported to the Authority on the conditions contained in regulations 3(2)a - 3(2)d and included in his report an

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<sup>93</sup>Ordinance No. 18 of 4 November 1972 at section 2(2) see also section 10(4).

<sup>94</sup>Law of 22 December 1992 at section 3.

<sup>95</sup>Section 8.

<sup>96</sup>Uniform Human Tissue Donation Act 1990 at section 7(6).

<sup>97</sup>Law of 19 November 1992 On the Transplantation of Organs and Anatomical Materials in Human Beings at section 12.

<sup>98</sup>Ordinance No. 16 of 1995 at section 5(4)d.

<sup>99</sup>*Ibid* at section 5(4)e. There must also be no payment or intention of payment that would contravene the Ordinance and an interviewing procedure is carried out with the prospective donor and recipient to check that these requirements and other ones relating to disclosure, as discussed in chapter 5, have been met (section 5(5) and 5(6)).

<sup>100</sup>ULTRA's satisfaction of these, and indeed any other factors, could be subject to judicial review. No such case has been brought but clearly proving that ULTRA was not satisfied would be very difficult.



account of any difficulties of communication with the donor or recipient and an explanation of how those difficulties were overcome. By virtue of regulation 3(1)c the requirements in regulation 3(2) do not apply "where the primary purpose of removal of an organ from a donor is the medical treatment of that donor."<sup>101</sup> The reference to coercion in regulation 3(2)c is mainly directed at preventing manipulation in the context of the organ market. However, it would also apply in other situations such as overwhelming family pressure to donate.<sup>102</sup> Interestingly regulation 3(2)c refers to consent being obtained *by* coercion (or the offer of an inducement). Hence, coercion / offer of inducement only has significance where it is the *cause* of donation i.e. but for it the prospective donor would not, on the balance of probabilities have donated.<sup>103</sup> This approach matches common law principles of voluntariness and undue influence<sup>104</sup> except in so far that 'offer of an inducement' is added within the legislative regime. In prospective LDT's involving persons who are defined as genetically related, ULTRA will not sanction donation caused by an offer of inducement. There is no clear principle that an LDT between genetically related persons caused by an offer of inducement (financial or otherwise) would necessarily be unlawful, although (given HOTA's main purpose is to ensure donation is gift motivated<sup>105</sup>) it would most likely be so on public policy grounds. This approach would not affect offers of an inducement which did not cause donation - for instance offers that were simply turned down. On the other hand, under the legislative regime, donation by a person not defined as genetically related to the prospective recipient would not be authorised where there had been an offer to pay travel expenses and other reasonable costs if this offer caused the donation! This may seem a bizarre result but on closer reflection it reflects the intention of the legislative regime that any prospective donor should be primarily motivated by non-financial factors. It is conceivable that someone might donate primarily out of a desire to travel to a place

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<sup>101</sup>This would mean that donation as part of domino heart transplants, for instance, would not be subject to the extra requirements of regulation 3(2), although still subject to the other provisions of the law (as to not obtaining removal by coercion etc.).

<sup>102</sup>See M.Evans, 'Organ Donation Should Not be Restricted to Relatives,' *J Med Ethics*, 1989, 15, 17.

<sup>103</sup>No test for causality is given under the HOTA or the pursuant regulations. The 'But For' test, being the main test used in negligence cases would normally be relied on.

<sup>104</sup>See Re T (adult: refusal of medical treatment)[1992] 4 All ER 649 at 6C(ii)b.

<sup>105</sup>See e.g. section 1(a) which makes it an offence to sell organs.



free of charge and have expenses paid for.<sup>106</sup> Whether, a donation in this situation would be unlawful in common law (on grounds of public policy) is not entirely certain since there is no great 'evil' to be prevented.

### **6.3.3. The Withdrawal of Consent to Donation in LDT.**

The ability to withdraw consent at any time is integral to the self-determining rights of potential donors and is a general principle of law. Many jurisdictions specifically uphold this principle within transplant law including Algeria,<sup>107</sup> Bolivia,<sup>108</sup> Canada,<sup>109</sup> Columbia,<sup>110</sup> France,<sup>111</sup> Hong Kong,<sup>112</sup> Hungary,<sup>113</sup> Kuwait,<sup>114</sup> Mexico,<sup>115</sup> Panama,<sup>116</sup> Portugal,<sup>117</sup> Romania,<sup>118</sup> Slovenia,<sup>119</sup> Slovakia,<sup>120</sup> Spain,<sup>121</sup> Tunisia,<sup>122</sup> the Australian states of Northern Territory,<sup>123</sup> Queensland,<sup>124</sup> South Australia,<sup>125</sup> Tasmania,<sup>126</sup> and Western Australia,<sup>127</sup> and, implicitly, Poland.<sup>128</sup> UK law, for donations not between

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<sup>106</sup>Especially, for instance, if this was a way to come from a far off country to stay/live in the UK.

<sup>107</sup>Law No. 85-05 of 16 February 1985 at section 162.

<sup>108</sup>Regulations On the Use of Human Organs and Tissues 15 March 1982 at section 12.

<sup>109</sup>The Uniform Human Tissue Donation Act 1990 at section 9(2).

<sup>110</sup>Uniform Human Tissue Donation Act 1990 at section 9(2).

<sup>111</sup>Section 2 of Decree No. 78-501 of 31 March 1978 For the Implementation of the Law of 22 December 1976 On the Removal of Organs. See also Article 671-3 of the 1994 law which states that, "consent may be withdrawn without formality and at any time." (*IDHL*, 1994, 45(4), 473-482 at p475).

<sup>112</sup>Ordinance No. 16 of 1995 at section 5(4)d for donations which are not between spouses of 3 or more years standing or close genetic relatives.

<sup>113</sup>Ordinance No. 18 of 4 November 1972 at section 2(3) stating that, "at any time prior to removal of the organ, the donor may, unconditionally withdraw his consent, in any manner whatsoever."

<sup>114</sup>Decree-Law No. 55 of 20 December 1987 On Organ Transplantation at section 4.

<sup>115</sup>Federal Regulations of 16 August 1976 at section 26.

<sup>116</sup>Law No. 10 of 11 July 1983 at section 19.

<sup>117</sup>Law No. 12 of 22 April 1993 at section 8(6).

<sup>118</sup>Law of July 1978 at section 132 now contained in Article 4(3) of 1996 Law.

<sup>119</sup>Article 10 of 1996 Law.

<sup>120</sup>Law of 24 August 1994 at section 46(1).

<sup>121</sup>Crown Decree No. 426 of 22 February 1980 at section 4. Additionally this section states that 24 hours must elapse between the signature of the document and the removal of the organ. See Casabona, *The Living Donor in Spanish Law* - manuscript held at EUROTOLD.

<sup>122</sup>Law No. 91-22 of 25 March 1991 at section 9.

<sup>123</sup>No. 121 of 1979 at section 16.

<sup>124</sup>The Transplantation and Anatomy Act 1979-1984 at section 21.

<sup>125</sup>The Transplantation and Anatomy Act 1983 at section 16.

<sup>126</sup>The Human Tissue Act 1985 at section 22.

<sup>127</sup>Act No. 116 of 1982 at section 14.

<sup>128</sup>The law requires that the potential donor be informed of the consequences of withdrawal of consent during the last phase of preparation of the recipient for the transplant procedure. This is perfectly



persons defined as genetically related under HOTA, requires that ULTRA be satisfied that the proposed donor understands his / her entitlement to withdraw consent and has not done so.<sup>129</sup> Medical practitioners submit proposed genetically unrelated donations before ULTRA who must be satisfied that the donor understands his / her right to withdraw consent at any time.<sup>130</sup> Failure on the part of the practitioner to ensure the donor understands this right constitutes a statutory offence. Of course such a failure would result in liability at common law anyway, but what the existence of this legislative regime adds is the reality of independent scrutiny of this and other issues with all genetically unrelated LDT's. Hong Kong's Ordinance states that the Board authorising organ LDT's not legislatively defined as between genetic relative or spouses of 3 or more years standing<sup>131</sup> be satisfied that after giving consent there was no subsequent withdrawal of consent<sup>132</sup>

#### **6.3.4. Independent Authorisation of LDT's.**

Some transplant laws include provision for independent authorisation of LDT, partly to ensure the voluntariness of donation. There are variations in who is assigned the authorising role and in their level of independence from the recipient team. Finnish law requires the approval of the National Board of Health;<sup>133</sup> Slovakia's law a special advisory committee opinion;<sup>134</sup> Hungarian law three physicians not involved in the

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reasonable if done in a neutral way but it could be done in a manner which pressurises the potential donor to carry on despite no longer really wanting to donate. In this situation the donation could be prevented by the fact that it can be said that consent has no longer been freely given. Law of 26 October 1995 at Article 9(1) at point 8 read in conjunction with point 7.

<sup>129</sup>Human Organ Transplant Regulations 3(2)d.

<sup>130</sup>Ibid.

<sup>131</sup>Ordinance No. 16 of 1995 at section 5(4)d.

<sup>132</sup>Ibid.

<sup>133</sup>Law No. 355 of 26 April 1985 On the Removal of Human Organs and Tissues for Medical Purposes at sections 2 and 3 respectively.

<sup>134</sup>"It being the task of this committee to examine the legitimate chances of success of the removal and transplantation of an organ, as well as the extent to which the benefit for the recipient is likely to outweigh any detriment to the donor. Removal may not be performed if it is anticipated that this will seriously jeopardise the donor's state of health." Law of No.277 of 24 August 1994 at section 46(2). See *IDHL*, 1995, 46(2), 151-157 at 155.



removal and transplantation procedures;<sup>135</sup> and Syrian Arab Republic law a commission of three medical specialists other than the physicians carrying out the removal procedure.<sup>136</sup> As already discussed, UK, Hong Kong and Indian law also require independent authorisation of LDT's involving certain types of donor-recipient relationship. Some laws require authorisation by an independent body for minor or adult incompetent donation.<sup>137</sup>

#### **6.3.5. Voluntariness and Restrictions on Donor's Due to Their Status.**

In some cases, law restricts donation by persons in terms of their status - most often where this involves capacity to donate<sup>138</sup> but in some instances in order to help ensure voluntariness/freedom from undue influence in donation. Such provisions are typically aimed at people with institutional status.

Jurisdictions prohibiting prisoners from being living donors include Slovakia,<sup>139</sup> Panama<sup>140</sup> and Paraguay.<sup>141</sup> These restrictions are put in place partly to protect prisoners from being exploited in their vulnerable position. However, it seems overly restrictive not to allow prisoners to donate to family as allowed under Mexican law (spouse, concubine or relative)<sup>142</sup> and Bolivian law (immediate blood relatives or relatives by marriage").<sup>143</sup> Bolivian law is to be commended on being based on the *de facto*

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<sup>135</sup>Transplant must be justified in the view of these physicians. Ordinance No. 18 of 4 November 1972 of the Minister of Health for the Implementation of the Provisions of Law No. II of 1972 On Health Relating to the Removal and Transplantation of Organs and Tissues at section 1(2).

<sup>136</sup>The requirement is only that they find the operation to be necessary for the recipient. Law No. 31 of 23 August 1972 On the Removal and Transplantation of Organs from the Human Body at section 2(5). The Canadian Model law requires that an independent assessment be carried out in cases where non-regenerative tissue is being donated.

<sup>137</sup>See chapter 7.

<sup>138</sup>See chapter 7.

<sup>139</sup>Law of 24 August 1994 at section 46(1), *IDHL*, 1995, 46(2), 151-157 at 155 states that, "removal may not be performed if the donor is serving a prison sentence."

<sup>140</sup>Law No. 10 of 11 July 1983 at section 22 prohibits donation by persons subject to restrictions on their legal rights such as prisoners and other persons deprived of their liberty.

<sup>141</sup>Law No. 836180 of 15 December 1980 Promulgating the Health Code at section 279 prohibits 'detainees' from being donors.

<sup>142</sup>Decree of 25 April 1987 Revising and Amending the General law on Health at section 328.

<sup>143</sup>Regulations of March 1982 at section 5.



voluntariness of prisoners and other persons of restricted liberty.<sup>144</sup> This approach is also taken in common law. The Michigan Circuit Court in the US case of Kaimowitz v Michigan Department of Mental Health 42 USLW 2063 [1973] (Mich Cir Ct) emphasised that pressure can easily be overbearing in a mental hospital context which starts off as inherently unequal. This was a case where on the facts the patient was held not to have given voluntary consent to psychosurgery. The English Court of Appeal referred to Kaimowitz in the case of Freeman v Home Office (No 2) [1984] QB 524. Freeman was a case involving a prisoner where on the facts the consent was held to be valid but it was accepted an institutional setting could make apparent consent invalid.<sup>145</sup>

The Courts are obviously prepared to scrutinise decisions within institutional contexts very carefully and will no doubt be particularly guarded where the proposed procedure is serious and invasive, as it was in Kaimowitz, and more so if, as in living donation, there is no therapeutic necessity for the procedure to be undergone and a higher than normal risk of inducements (for instance the possibility of early release for a prisoner) becoming the basis of decision-making. Under the UK legislative regime ULTRA would not authorise a donation by a prisoner to a person (s)he was not defined as genetically related to if early release had been offered as an inducement and was acting as the cause for the decision to donate. The need to establish that the donation was voluntary would lead to a close examination of motivations of possible altruism and/or family solidarity.

#### **6.3.6. Voluntariness and Restrictions on Donor-Recipient Relationship.**

Article 4 of the Council of Europe Resolution 78(29) states that removal of substances which cannot regenerate must be confined to transplantation between genetically related persons barring exceptional cases where there are good chances of success. WHO

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<sup>144</sup>"persons under special disciplinary condition or otherwise detained in closed institutions may donate organs and tissues only of their own free will ... " Regulations of March 1982 at section 5.

<sup>145</sup>Nethertheless on the facts of the case Kennedy and Grubb have suggested that, "it could be said that the court dismissed the argument that the 'institutional setting' deprived him of his free will too readily." Medical Law: Text With Materials, Ibid at 241.



Guiding Principles take a similar approach stating that in general donors should be genetically related to the recipients although exceptions may be made in the case of transplantation of bone marrow and other regenerative tissue.<sup>146</sup>

Some jurisdictions simply limit LDT's from living donors to recipients with whom they have an existing relationship, whether genetic, familial or emotional. Other jurisdictions subject donations involving certain types of donor-recipient relationship to more stringent qualifying criteria and/or a process of authorisation. The general approach is that the more distant a potential donor is emotionally and genetically the more likely the law is to prohibit or place extra restrictions on it; the goal being to reduced likelihood of both involuntary *and* commercially motivated donation (which are often viewed as more likely the more distant the relationship of the prospective donor-recipient pair). Costa Rican law limits donors to giving to relatives,

"up to the fourth degree of consanguinity or up to the third degree of affinity, or of his spouse"<sup>147</sup>

Portuguese law restricts living donation of non-regenerative substances to relatives of the donor up to the third degree.<sup>148</sup> The law of the Russian Federation is ambiguous but appears to restrict donation from living donors to persons with whom there is a genetic relationship, apart from cases of bone marrow donation.<sup>149</sup> French law generally restricts donation of organs as a whole to the nuclear family unit, except in the case of bone marrow transplantation.<sup>150</sup> However, it allows donation between spouses in emergency cases.<sup>151</sup> Italian law restricts living kidney donation to the nuclear family unit (including half-brothers and sisters).<sup>152</sup> In Slovenia donation of non-reviving body

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<sup>146</sup>Guiding Principle 3.

<sup>147</sup>Law No. 5560 of 20 August 1974 On Human Transplants at section 15.

<sup>148</sup>Law No. 12 of 22 April 1993 at section 6(2).

<sup>149</sup>Law of 22 December 1992 at section 11.

<sup>150</sup>Article 671-3 *ibid*.

<sup>151</sup>Law No. 94-654 of 29 July 1994.

<sup>152</sup>Law No. 458 of 26 June 1967 Concerning the Transplantation of Kidneys From Living Donors.



materials appears to be limited to liver segment and kidney for transplantation into genetic or familial relatives.<sup>153</sup>

Some jurisdictions subject LDT's involving certain donor-recipient relationships to more stringent qualifying criteria. The recent Venezuelan law generally restricts LDT to first degree blood relatives but allows the National Executive to determine that a wider range is acceptable.<sup>154</sup> The new Swedish law restricts LDT to situations where "the donor is related to the potential recipient or if he is particularly close to him for some other reason" and other persons only in "special cases."<sup>155</sup> Without explicitly requiring the donor's decision to be voluntary some jurisdictions concern themselves with freedom from pressure in decision-making. Russian Federation law<sup>156</sup> and Belarus draft law<sup>157</sup> thoughtfully attempt to exclude pressured donations by excluding donations by a person who is dependant on the recipient<sup>158</sup> as well as donations that have been coerced.

Some jurisdictions rely primarily on an authorising body to determine and/or apply restrictions on specific classes of donor-recipient relationship. The general approach seems to be to restrict and more closely scrutinise donation by persons who do not have a close blood or at least legal tie with the recipient. The main purpose of such an approach is usually to prevent commercially motivated donations and thereby protect the reputation of transplantation. Trade is more likely to happen outside the genetic relative context. However a clear subsidiary purpose of such provisions is to ensure voluntariness - the concern being that manipulation and coercion can occur outside the genetic relative context. Coercion and manipulation can, of course, also occur within the genetic relative context - a point that has not gained much recent attention but has been documented in the psychological literature for decades. Close family ties can be

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<sup>153</sup>Law of 1995 at Article 8.

<sup>154</sup>Law of 19th November 1992 On the Transplantation of Organs and Anatomical Materials in Human Beings, at section 11 (*IDHL* 1995, 46(3) at 329-330).

<sup>155</sup>Law No. 831 of 8 June 1995 at section 7.

<sup>156</sup>Law of 22 December 1992 at section 3.

<sup>157</sup>Section 8.

<sup>158</sup>Either because of their functions or in any other manner.



more coercive in a subtle and manipulative way than more distant ties which offer more potential to produce more purely altruistic donations.

Hong Kong's Ordinance allows donation only by close genetic relatives,<sup>159</sup> spouses of 3 years standing<sup>160</sup> and those given special authorisation to donate by a board set up under the law<sup>161</sup> (this board can only take referrals from the responsible clinicians, not potential donors and recipients themselves<sup>162</sup>). Among the criteria imposed for donations requiring approval are that a registered medical practitioner, who is not the person removing the organ must explain to the donor and recipient about the procedure, the risk involved and the entitlement to withdraw consent at any time and this information must be understood.<sup>163</sup> The donor must have given consent without coercion, offer of inducement or subsequent withdrawal of consent.<sup>164</sup> An interviewing procedure is also carried out with the potential donor and recipient principally to check that requirements have been met.<sup>165</sup>

UK has a provision similar to Hong Kong, again partly aimed at ensuring voluntariness. Under section 2(1)a HOTA 1989 it is an offence for a surgeon to remove an organ from a person who is not genetically related to the intended recipient. Section 2(1)b also prohibits the transplantation of an organ into a recipient who is not genetically related to the donor. The definition of genetic relative excludes people who are distant blood relatives as well as spouses and other persons who are emotionally related.<sup>166</sup> Section

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<sup>159</sup>Ordinance No. 16 of 1995 To Prohibit Commercial Dealings in Human Organs Intended For Transplanting, to Restrict the Transplanting of Organs Between Persons Who Are Not Genetically Related, to Regulate the Importing of Human Organs Intended for Transplanting and For Supplementary Purposes Connected With These Matters. The Human Organ Transplants Ordinance at section 5 (1). Section 5(2) defines those who have sufficient genetic relationship the nuclear family unit plus uncles, aunts and first cousins. These relatives can be full or half blood.

<sup>160</sup>Section 5 (1) *ibid*.

<sup>161</sup>Section 5 *ibid*.

<sup>162</sup>Section 5(4)a *ibid*.

<sup>163</sup>Section 5(4)c *ibid*.

<sup>164</sup>Section 5(4)d *ibid*. There must have been no payment or intention to pay that would be prohibited under the Ordinance (section 5(4)e).

<sup>165</sup>Section 5(5) and section 5(6).

<sup>166</sup>Genetically related donors are classified under the act as the following relatives of the recipient: (a) his natural parents and children, (b) his brothers and sisters of the whole or half blood, (c) the brothers and sisters of the whole or half blood of either of his natural parents, and the natural children of his brothers and



2(3) of the Act allows the Secretary of State to pass regulations providing that the prohibition on LDT between non-genetically related persons<sup>167</sup> shall not apply where:

"(a) such authority as is specified in or constituted by the regulations is satisfied-

(i) that no payment has been or is to be made in contravention of section 1 above;<sup>168</sup> *and*

(ii) that such other conditions as are specified in the regulations are satisfied; *and*

(b) such other requirements as may be specified in the regulations are complied with."

The Human Organ Transplants (Unrelated Persons) Regulations<sup>169</sup> passed pursuant to section 2(3) of HOTA set up ULTRA as the body to scrutinise non-genetically related donation. Proposed LDT's between distant blood relatives and emotionally relatives such as spouses can be brought before ULTRA and permitted providing certain conditions are fulfilled.<sup>170</sup>

General Medical Council Guidance on the application of the Act is that doctors have a duty to establish beyond doubt the presence of consanguinity or a close and enduring relationship between the donor and the recipient.<sup>171</sup> The key behind the scrutiny of donations that are not close genetic related was Parliaments concern to ensure that all donations are altruistic.<sup>172</sup> However, donation between grandparents and grandchildren is perhaps unwittingly subject to ULTRA authorisation (through not being within the

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sisters of the whole or half blood or of the brothers and sisters of the whole or half blood of either of his natural parents. The PhD uses the phrase 'close genetic relationships' to describe these categories. Other categories are 'distant genetic relatives,' emotionally related donors and strangers. The scientific tests for establishing genetic relationship under the Act are undergoing revision through having proved to be practically unworkable.

<sup>167</sup>As defined in above reference.

<sup>168</sup>i.e. in contravention of section 1 of HOTA which regulates commercial dealings in human organs.

<sup>169</sup>S.I. 1989 No 2480.

<sup>170</sup>These conditions relate primarily to disclosure, capacity, voluntariness and commerce in donation and are discussed in the corresponding chapters of the PhD.

<sup>171</sup>The Guidance adds that doctors, "should consider seeking advice from professional bodies, including national and international transplantation societies, on the tests needed to establish consanguinity and on the circumstances in which unrelated live donor transplants may be considered." General Medical Council Guidance for Doctors on Transplantation of Organs From Live Donors, *General Medical Council Supplement News Review*, December 1992 at point 7.

<sup>172</sup>HC Deb, 6th July 1989.



legal ambit of 'genetic relative' donation under the Act<sup>173</sup>); it cannot have been seriously considered that such donation were any more susceptible to commercial motivation or pressure than those involving the direct nuclear family unit.<sup>174</sup> 'Gifts' between genetic relatives can sometimes constitute payment under the Act and hence be an offence but were probably less of a concern in passing the Act than fully-blown trade.

Indian law allows donations from persons outside the nuclear family unit with the prior consent of the Authorisation Committee where the donation is based on donor affection or attachment to the recipient or any other special reasons.<sup>175</sup> It is not unusual for requirements on the relationship the donor must have with the recipient to operate informally at the centre level in countries without the use of specific legislative provisions. For instance, in Germany it was common practice only to allow intra-nuclear familial genetically related living donations although now a more adventurous approach is being taken in some centres, particularly with the use of spouses.<sup>176</sup>

Prohibiting donations where the donor and recipient have an existing relationship seems overly restrictive. However, subjecting certain forms of donation to the prior approval of an authorising committee is an acceptable step - not only to ensure adequate checking of such matters as voluntariness from a body which will build up expertise in this area but also to encourage practitioners to use such forms of LDT by giving them the confidence that the ethics of such donations will be given an ethical seal of approval from an expert body (in turn providing them with a means to deflect any criticism of practice).

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<sup>173</sup>See Kennedy and Grubb *Medical Law: Text With Materials*, Butterworths, 1994 (2nd edition), 1092

<sup>174</sup>The additional point can be made that donations within the family can be the consequence of pressure, guilt and other motivations - i.e. they are not necessarily altruistic; this discussion about the merits of restricting different classes of donation is continued in chapter 7.

<sup>175</sup>The terms and conditions of operation of which is determined by Central Government. An Act (No. 42 of 1994) To provide For the Regulation of Removal, Storage and Transplantation of Human Organs for Therapeutic Purposes and for Matters Connected Therewith Or Incidental Thereto (The Transplantation of Human Organs Act 1994 at section 9 ((IDHL, 1995, 46(1) at 34-37).

<sup>176</sup>Centres taking a more adventurous approach include Munich and Freiburg.



## **6.4. Conclusions.**

Most external pressures are not readily perceivable and quantifiable in their impact on the decision-maker. Nevertheless, law can to a certain extent protect against external pressures overbearing the will of decision-makers; a proviso being that decisions should only be overturned where a high standard of proof is satisfied.

Whilst the demand for revised legislation of voluntariness in LDT is not very high it could bring to bear greater certainty in this area - particularly if detailed guidance for interpreting voluntariness were included in order to supplant the need to rely on general principles for interpretation. The development of regulation could include examining voluntariness in the context of the recipient and more systematic consideration of different classes of donor - including adoption of an authorising committee approach to approving certain forms of LDT such as that used in Hong Kong. In addition, this issue can be addressed within a code of practice which addresses practical methods of meeting regulatory requirements and minimising all forms of pressure.

Further research is needed in this area is needed - particularly to explore the dimensions of recipient decision-making and highlight the advantages and disadvantages of the different processes that exist from centre to centre in approaching prospective donors. Clearly practitioners have an important role, not just in following the minimum legal standard but developing best practice in protecting donors as far as possible from both their own impulsiveness and unconscious motivations and pressures from external sources such as family members and practitioners themselves. The development of centre protocols could be a key feature here.



## Chapter 7 Minor and Adult Capacity and Consent to LDT.

### Chap 7.1. Introduction.

Use of incompetent adults as living organ donors is extremely rare and use of minors is relatively rare,<sup>1</sup> although attitudes surveys amongst transplant professionals in the US, Great Britain and now (through EUROTOLD) Europe as a whole indicate increased scope for use.<sup>2</sup> However, LDT by these classes of donor is of special legal and ethical significance. Conflicts between paternalism and autonomy and between deontological theory and consequentialism arise when people lose the right to self determination in a medical decision through being classified as incapable of consenting to that decision based on their mental condition, insufficient mental development or maturity *or even simply because* of minority or having a mental condition/lack of development (i.e. *without any finding of incapacity*). These conflicts are amplified in living organ donation as it is not a treatment,<sup>3</sup> will cause some detriment and is primarily designed for the benefit of another. Can donation by an incapacitate be justified as in his/her best interests rather than simply of utilitarian value? If the answer is yes, there is the question of what conditions use should be subject to. Should donation by competent minors and by adults with mental disability/illness impairing their judgement but still competent be subject to special restrictions or treated in the same fashion as organ donation by a 'normal' adult. Should decisions in cases not involving a 'normal' adult be subject to judicial involvement or oversight or left in the hands of the prospective donor, his/her family and transplant practitioners?

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<sup>1</sup>In 1992 J.K.Mason ('Legal Aspects of Organ Transplantation,' in C Dyer (ed) *Doctors, Patients and the Law*, 1992) reported that in Europe in the preceding 10 years 5 minors had been used in Eurotransplant, one each in UK and Eire and none in Scandinavia or France. Considerably more minors become cadaver donors. In the UK in 1992 11% of cadaveric kidney donors were under the age of 16 - over half of these were under 11 (UKTSSA Annual Report 1992 - see also J.Alexander et al, *The Use of Marginal Donors for Organ Transplantation: The Older and Younger Donors*, *Trans Proc*, 1991, 23(1) at 905). Paediatric liver cadaveric donation also frequently occurs. Living donor minors are used more frequently in the USA - Spital's 1987 survey of US Transplant Centres found 13% of responding centres had performed at least one non-twin minor transplant within the preceding 5 years (*Unconventional Living Kidney Donors: Attitudes and Use Among Transplant Centers*, *Transplantation*, 1989, 48(2), 243-248). The use, as living organ donors, of person's incapacitate to donate by reason of mental illness or disability is almost unheard of in Europe although there have been several instances in the US - some of them the subject of high profile cases - see 7.4.3.

<sup>2</sup>These surveys are discussed further in chapter 10.

<sup>3</sup>See *Re W (A Minor) Medical Treatment* [1992] 3 WLR 758 at 767F.



A framework for addressing these issues flexibly is provided under general principles of law. In some cases transplant law has reduced the flexibility by, for instance, excluding certain donors, in other cases it has merely confirmed general principles e.g. by asserting the need for consent.

One of the critical factors in the legal position is whether or not the donor has reached majority, as this brings with it a presumptive right of self-determination over the decision of whether or not to donate. Under the general law most jurisdictions will define a minor as passing into majority at age 16 or 18 for the purposes of medical treatment. Those transplant laws specifying an age of majority in the context of living organ donation, may do so simply to confirm the position within that jurisdiction for medical treatment in general *or* to define a different, usually higher, age - such as 21. English law is somewhat unusual in arriving almost accidentally at a lower age of majority in medical decision-making generally than for living organ donation specifically. The general position of English law, under section 8 of the Family Law Reform Act 1969, is that capacity is rebuttally presumed to exist with 16 and 17 year olds. However, in the context of organ LDT, Section 8 is only applicable to reception and not donation because it only refers to medical '*treatment*'.<sup>4</sup> This means, as affirmed in Re W (A Minor) Medical Treatment [1992] 3 WLR 758,<sup>5</sup> that the rebuttable presumption of capacity for young people donating an organ or tissue applies from the age of 18 *not* the age of 16 under English law.<sup>6</sup>

Of course, unless legislation states the contrary, persons under 18 can be *de facto* capacitate to donate an organ but this *does not necessarily* confer on them a presumptive right of self-determination. This brings us on to the second factor on which a legal position can hinge - the definition of capacity. Not surprisingly, there are differences in approach between minors and adults<sup>7</sup> although commonalities are that minors and adults

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<sup>4</sup>Subsection 2 states that in section 8 "surgical dental or medical treatment includes any procedure undertaken for the purposes of diagnosis and this section applies to any procedure (including in particular the administration of an anaesthetic) which is ancillary to any treatment as it applies to that treatment." The emphasis is on treatment which organ donation is not.

<sup>5</sup>At 767F.

<sup>6</sup>Ibid - i.e the presumption of capacity reverts back to the age of 18 in accordance with general principles of law relating to the age of majority.

<sup>7</sup>M.Gunn, The Meaning of Capacity, *Med Law Review*, 1994, 2(1) at 8.



can both be deemed legally capable of making some decisions and not others and capacity can vary over time.<sup>8</sup>

The House of Lords case of Gillick v West Norfolk and Wisbech Area Health Authority (1985) 3 All ER 402<sup>9</sup> established that a minor has capacity where (s)he has sufficient understanding and maturity to consent to the particular procedure in question.<sup>10</sup> Despite organ donation not being a treatment, the Gillick principle<sup>11</sup> applies to it according to Re W.<sup>12</sup> 'Sufficient' maturity has not been fully defined;<sup>13</sup> which is somewhat inevitable because it will depend on the procedure in question and will often be influenced, though not determined, by increasing age. Clearly it would be harder, for instance, for a minor to be sufficiently mature to make a decision about living organ donation than to make one about blood donation and the younger the minor the less likely (s)he would be sufficiently mature to make a decision about either.

While an adult starts with a presumption of capacity to make all medical and other decisions<sup>14</sup> this presumption can be rebutted. Legal principles for determining whether

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<sup>8</sup>However, in the case of an adult at least, a person with fluctuating capacity will not be deemed capacitate even if (s)he has expressed a clear decision during a period of lucid capacity. In Re R [1992] Fam. 11 this scenario formed the basis of a decision relating to a 15 year old girl being forcibly administered anti-psychotic drugs when her ability to consent was deemed fluctuating.

<sup>9</sup>See Bainham, *The Judge and The Competent Minor*, *LQR*, 1992, 108, 194.. This case concerned the hypothetical capacity of a 14 year old girl to take the contraceptive pill (Hypothetically because essentially her mother was bringing the case not out of genuine fear that her daughter would take the contraceptive pill but to establish certain points of law on the matter and with regard to a department of health circular relating to girls under 16 being prescribed the contraception). The House of Lords decided that she had capacity to consent to taking the contraceptive pill. The decision allows for flexibility in the treatment of the capacity of minors. Thus in principle a decision to donate an organ by a person under the age of 16 could be legal, provided the young person at issue

<sup>10</sup>See Lord Scarman's judgment in Gillick [1985] 3 All ER 402. Lord Scarman's flexible approach has been adopted in a number of other countries see for example the Court of Appeal decision in Alberta, Canada in C v Wrent [1987] 35 DLR (4th) 419 (Alta CA).

<sup>11</sup>Gillick v West Norfolk and Wisbech Area Health Authority (1985) 3 All ER 402 (HL). See Bainham, *The Judge and The Competent Minor*, *LQR*, 1992, 108, 194. For the legal genesis of this approach see Lord Scarman's judgment in Gillick [1985] 3 All ER 402. Lord Scarman's flexible approach has been adopted in a number of other countries see for example the Court of Appeal decision in Alberta, Canada in C v Wrent [1987] 35 DLR (4th) 419 (Alta CA)

<sup>12</sup>3 WLR 758 at 767 and 772 at para C per Lord Donaldson. A number of legal academic articles have also taken this position. See e.g. Price and Garwood-Gowers, *Transplantation From Minors*, *Contemporary Issues in Law*, 1996, 1(1), 1-27, Mason and McCall-Smith (*Law and Medical Ethics*, *Butterworths*, 1991, 373) and M.Brazier (*Medicine, Patients and The Law*, *Penguin*, 1992 (2nd ed), 421

<sup>13</sup>M.Gunn, *The Meaning of Capacity*, *Med Law Review*, 1994, 2(1) at 8.

<sup>14</sup>See for instance the law of Scotland on this matter discussed in D.M.Walker, *Principles of Scottish Private Law*, *Clarendon Press*, 1982 (3rd edn), Vol 1.



an adult has capacity are complex and unsettled.<sup>15</sup> A general point is that the finding of incapacity to make a decision is usually related to factors like mental illness or disability or to temporary factors such as shock, severe fatigue, pain or drugs being used in his treatment.

## **7.2. Minors and LDT.**

The legal position of living organ donor transplantation by minors was first considered 40 years ago by the Massachusetts Supreme Judicial Court in Masden v Harrison.<sup>16</sup> Since then it has been considered in English and US cases and within most transplant laws. In many jurisdictions the legal position is derived from a combination of analysing transplant legislation and general principles. For instance, under HOTA, non-genetically related living organ donation is illegal in the UK unless it gains the prior authorisation of ULTRA. Amongst other things ULTRA must be satisfied that the donor is competent.<sup>17</sup> However, non-genetically related minor living donation is still subject to common law principles of liability in the same way as its genetically related counterpart.

### **7.2.1. Living Organ Donation by Incompetent Minors.**

Many transplant laws are framed in such a way as *not* to exclude the possibility of living organ donation by incompetent minors. Such donors also have the potential for acceptance under general principles of law and have indeed become living organ and tissue donors in the US although only tissue and blood donors in the UK.

#### **7.2.1.1. Conditions For Donation by Incompetent Minors Under Transplant Legislation.**

Jurisdictions with transplant legislation allowing the normal range of organs to be donated by incompetent minors include: Argentina,<sup>18</sup> Cuba,<sup>19</sup> Malawi,<sup>20</sup> South

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<sup>15</sup>In regard to adults the recent Law Commission Report on Mentally Incapacitated Adults stated that “(i)t is widely recognised that, in this area, the law as it now stands is unsystematic and full of glaring gaps. It does not rest on clear or modern foundations of principle.” HMSO, Law Comm No.231, 1995 at p1.

<sup>16</sup>Eq. No 68651 (Mass, June 12,1957). Confirmed in the same year by Huskey v Harrison Eq. No. 68666 (Mass., Aug. 30 1957) and Foster v Harrison Eq. No. 68674 (Mass., Nov. 20, 1957).

<sup>17</sup>Section 2(3)a.

<sup>18</sup>Section 14 *ibid*. Section 18 specifies a list of people who are able to consent in order of priority topped by a spouse.



Africa,<sup>21</sup> Sweden<sup>22</sup> and Syrian Arab Republic (where between twin brothers only).<sup>23</sup> In several other jurisdictions incompetent minors appear to be able to donate liver segment by virtue of the fact this it is regenerable or replacable body material (Australian laws generally,<sup>24</sup> Belgium,<sup>25</sup> Finland,<sup>26</sup> Portugal,<sup>27</sup> Slovenia,<sup>28</sup> Sri Lanka,<sup>29</sup> Zimbabwe,<sup>30</sup> Argentina,<sup>31</sup> South Africa,<sup>32</sup> Cuba,<sup>33</sup> Malawi<sup>34</sup> and the Syrian Arab Republic<sup>35</sup>). This was clearly not an intended result (because liver segment donation carries more prospective detriment than some forms of donation of non-regenerative material - e.g.

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<sup>19</sup>Decree No.139 of 4 February 1988 section 81.

<sup>20</sup>Section 11 The Anatomy Act 1990.

<sup>21</sup>Section 18 (b)(ii).

<sup>22</sup>Law No. 831 of 8 June 1995 (*IDHL*, 1996, 47(1)).

<sup>23</sup>If the donor is under 21 the parent(s) must consent. Law No. 31 of 23 Aug 1972 On the Removal and Transplantation of Organs from the Human Body (*Recueildes lois et de la Legislation Financiere de la Republique Arabe Syrienne*, Sept 1972, p2-4).

<sup>24</sup>Queensland The Transplantation and Anatomy Act 1979-1984 at section 12(b) by implication; South Australia The Transplantation and Anatomy Act (1983) section 12(a); Western Australia The Human Tissue and Transplant Act 1982 (No.116 of 1982) at section 13(1); Tasmania The Human Tissue Act 1985 at section 7(a); and Tasmania. However in the Northern Territory The Human Tissue Transplant Act 1979 (No. 121 of 1979) at section 9 excludes donation by those under 18 and New South Wales The Human Tissue Act 1983, s10 forbids it by omission from specified permissions. In Canada this position is recommended for provinces under the model law, Uniform Human Tissue Donation Act 1990 section 5(1) and 6(1). The age of majority is 16. If there is reason to believe the minor may not "understand the nature and consequences of transplanting tissue" an independent assessment must be carried out. This assessment will take into account a number of factors and then a choice will be made (section 8). The decision may be appealed to the Supreme Court of Canada. The Human Tissue Donation Act 1992 for Prince Edward Island (Canada) has a similar provision (section 7(1)) although no independent assessment scheme is applied. If a minor does not understand the procedure (s)he will be limited to the donation of bone marrow with parental/guardian consent required (section 7(2))

<sup>25</sup>Law of 1986 (sections 5-7).

<sup>26</sup>Law Number 355 of 26 April 1985. Persons under the age of 18 may donate non-renewable tissue with the consent in writing of their guardian or trustee and the approval of the National Board of Health and provided the donor does not object. The donor's opinion of the intervention shall be established insofar as is possible having regard to his age and level of development. An expert in child psychology or paediatrics must submit a report to the National Board of Health to accompany the application for approval which must be submitted to the Board before the living donation in question can proceed.

<sup>27</sup>Law No. 12 of 22 April 1993 On The Removal and Transplantation of Human Organs and Tissues section 6(3) and section 8(3).

<sup>28</sup>*Ibid.*

<sup>29</sup>Parents must consent if the donor is under the age of 21 or one of them if the other is incapacitate or otherwise the guardian. The Transplantation of Human Tissues Act, No. 48 of 1987 at sections 7 and 8.

<sup>30</sup>Parents / Guardian must give the consent if the donor is under the age of 18. Anatomical Donations and Post Mortem Examinations Act No. 34 of 1976 at section 12 particularly subsection (b).

<sup>31</sup>Section 14 *ibid.* Section 18 specifies a list of people who are able to consent in order of priority topped by a spouse.

<sup>32</sup>Section 18 (b)(ii).

<sup>33</sup>Decree No.139 of 4 February 1988 section 81.

<sup>34</sup>Section 11 The Anatomy Act 1990.

<sup>35</sup>Law No. 31 of 23 Aug 1972 On the Removal and Transplantation of Organs from the Human Body (*Recueildes lois et de la Legislation Financiere de la Republique Arabe Syrienne*, Sept 1972, 2-4).



donation of a single kidney) but there is a way round it which is to specify that removal must normally carry a minimal level of detriment - this would result, for instance in bone marrow donation being allowed and liver segment donation not being allowed. The only law that comes close to taking this approach is the Netherlands which amongst other conditions specifies that for living minors under 12 the removal of non-regenerable material must not have lasting effects on the donors health.<sup>36</sup>

The anomalous, more liberal treatment of living liver segment is also witnessed in the Council of Europe's 1978 Resolution<sup>37</sup> under which by virtue of being regenerative, it can be donated by an *incapacitate* exceptionally and provided there is no objection from the minor and his legal representative consents to it.<sup>38</sup> Contrastingly, non-regenerative material is restricted to special cases where a donor has the *capacity* for understanding, has consented to donation along with his legal representative and has authorisation of the appropriate authority.<sup>39</sup> In defence of the resolution it must be stated that it would have been drafted before lawyers would have conceived of the possibility of liver segment donation. The current re-examination of the Resolution will probably address the problem by avoiding the use of the term regenerative in this context.

In English law donation of an organ by a minor not within the ambit of 'genetic relative' as defined under HOTA and associated regulations regarding the use of non-genetically related donors is limited to donors who ULTRA is satisfied understand,

"the nature of the medical procedure and the risks, as explained by the registered general medical practitioner, and consents to the removal of the organ in question."<sup>40</sup>

Since all non-genetically related donations will go through ULTRA<sup>41</sup> it is almost inconceivable that an incompetent genetically unrelated minors will ever donate an organ

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<sup>36</sup>Law of 24 May 1996 at section 5(1) - see *IDHL*, 1996, 47(4) at 470.

<sup>37</sup>Resolution (78)29 on Harmonization of Legislations of Member States to Removal, Grafting and Transplantation of Human Substances. Adopted by the Committee of Ministers of The Council of Europe on 11 May 1978.

<sup>38</sup>Article 6(1).

<sup>39</sup>Article 6(2).

<sup>40</sup>The Human Organ Transplants (Unrelated Persons) Regulations 1989 (SI No 2480) at regulation 3(1) b.

<sup>41</sup>A doctor could theoretically do such a donation without ULTRA approval but practically is unlikely to do so since it would be an offence under the Act. Common law principles of liability would also be relevant if such a situation arose.



in the UK unless ULTRA makes an error of judgement.<sup>42</sup> The Act does not prevent incompetent minors from giving organs to genetic relatives,<sup>43</sup> perhaps partly because donation on behalf of a close genetic relative is easier to justify as in the direct psychological interest of the incapacitate.<sup>44</sup>

Use of living organ donation by incompetent minors is normally subject to conditions beyond consent by the person with legal authority to consent on behalf of the minor.<sup>45</sup> Many transplant laws have a whole range of requirements. For instance, in Finland persons under the age of 18 may donate non-renewable tissue with the consent in writing of their guardian or trustee and the approval of the National Board of Health and provided the donor does not object. The donor's opinion of the intervention shall be established insofar as is possible having regard to his age and level of development. Minor rejection of the procedure as a total bar. An expert in child psychology or paediatrics must submit a report to the National Board of Health to accompany the application for approval which must be submitted to the Board before the living donation in question can proceed.<sup>46</sup>

Some of the features in Finland's law which are common in transplant legislation include:

- the need for approval / non-refusal by the donor<sup>47</sup> thereby protecting him or her from the spectre of forced donation;
- the need for approval by a special designated person or body;<sup>48</sup> *and*

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<sup>42</sup>Such an error would be difficult to gain a successful judicial review of because ULTRA has only to be subjectively satisfied that consent has been given - there is no requirement for ULTRA's judgment to be reasonable or even that it has reasonable grounds to be satisfied - see discussion in chapter 4 on this point.

<sup>43</sup>HOTA 1989 section 2(3).

<sup>44</sup>Of course this does discriminate against people who may be close but not genetically related e.g. an adopted brother or sister.

<sup>45</sup>This requirement is explicitly stated in some legislation e.g. Sweden's law (Law No. 831 of 8 June 1995 at section 8) expressly requires parental / guardian support of the proposed donation and Finland's law requires consent in writing of their guardian or trustee (Law No. 355 of 26 April 1985).

<sup>46</sup>Law No. 355 of 26 April 1985.

<sup>47</sup>Portuguese law (section 8(4) of 1993) states that where the minor is "capable of understanding and able to express their wishes" the donation is "subject to their agreement." Slovenian law (Article 11 of 1996) states that if a minor is 15 years old or more and capacitate his / her consent is required and that in any case where any donor "explicitly contradicts" donation it is not allowed. Under Queensland law child agreement is required where the child is capable of understanding the nature effect of the removal of the tissue and the nature of the transplantation - this will refer only to competent minors if understanding the nature and effect of the removal is equatable with being competent to donate. Similar provisions exist in South Australia (section 13) and Western Australia (section 13(2)).

<sup>48</sup>Finland persons under the age of 18 may donate non-renewable tissue with the and the approval of the National Board of Health. An expert in child psychology or paediatrics must submit a report to the National Board of Health to accompany the application for approval which must be submitted to the Board



- the need for special justification (e.g. by restricting the level of permissible risk / harm to the donor and requiring a certain level of prospective benefits for the recipient).<sup>49</sup>

Occasionally there are restrictions, over and above those applying to competent adults, on who the material may be given to.<sup>50</sup>

#### 7.2.1.2. Conditions For Living Organ Donation by Incompetent Minors Under General Principles of Law.

##### The Approach Within Which Conditions Are Framed

Baron has detected 3 different judicial approaches to authorising minor organ donation:<sup>51</sup>

- necessitating informed consent;
- reviewing the parents' weighing of the relative costs and benefits of the operation to both children;<sup>52</sup> *and*
- the best interest test.<sup>53</sup>

Clearly the first approach would exclude organ donation by incompetent minors. In practice, while the presence of informed consent by a minor has been taken to be a strong

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before the living donation in question can proceed (Law No. 355 of 26 April 1985). Sweden's law (Law No. 831 of 8 June 1995 at section 8) states that the intervention must be authorised by the National Board of Health and Welfare and support of the physician empowered to decide on the removal and parental / guardian support. Belgium's law of 1986 (sections 5-7) requires that consents are obtained as follows:- 1. the consent of the donor if he is at least 15 years of age. 2. The consent of the spouse of the donor where the spouse is residing with him (in cases where the donor is under 18 but married). 3. The consent of the person(s) whose consent to the marriage of the minor is required (e.g. parents, guardian.). Slovenian law (Article 11 of 1996) requires prior ethical committee approval for the minor donation.

<sup>49</sup>Sweden's Law of 1995 requires the situation to be one where the recipient is unable to get compatible material from another person and there must be special grounds for removal (Law No. 831 of 8 June 1995 at section 8), Belgium's law of 1986 (sections 5-7) states that the transplant must be on behalf of a sibling Slovenian law (Article 11 of 1996) requires prior ethical committee approval for the minor donation and consent by the donor's legal representative or nearest relative. Under Queensland law there must be likely death of a member of the nuclear family without donation by the minor and the risk must be minimal (section 12c and d).

<sup>50</sup>This is more commonly stipulated solely in relation to tissues/regenerative material but Sweden's law, for instance, (section 8 *ibid*) limits donation of organs by minors to 'relatives.'

<sup>51</sup>Live Organ and Tissue Transplants from Minor Donors in Massachusetts, *Boston U Law Review* 1975, 55, 159 at p169.

<sup>52</sup>Nathan v Farinelli Eq. No. 74-87 (Mass., July 3, 1974).

<sup>53</sup>First used in 1957 Massachusetts decisions like Foster v Harrison, Eq.No. 68674 (Mas., Aug.30, 1957) and Huskey v Harrison, Eq. No. 68666 (Mass., Aug.30, 1957).



legitimizing factor it is not true to say that its absence has prevented organ donation by a minor. The two main tests that have been historically used for determining what medical treatment is acceptable on behalf of an incompetent minor are 'substituted judgement' and 'best interests.' The doctrine of substituted judgement involves decision-making on behalf of an incompetent minor or adult being made by reference to what the 'patient' would have done had they had capacity to decide. The doctrine appears to have little legal standing today in English law in the treatment of minors.<sup>54</sup> In the US the doctrine was often thought to have been the basis for allowing donation by a mentally 'disabled' adult in the case of Strunk v Strunk discussed later in this chapter. However, Little v Little (Tex Civ 1979), 576 SW 2d 493 at 498 concluded that,

"it is clear in transplant cases that courts, whether they use the term 'substituted judgement' or not, will consider the benefits to the donor as a basis for permitting an incompetent to donate an organ. Although in Strunk the Kentucky Court discussed the substituted judgement doctrine in some detail, the conclusion of the majority there was based on the benefits that the incompetent donor would derive, rather than on the theory that the incompetent would have consented to the transplant if he were competent. We adopt this approach."

The substituted judgement doctrine has subsequently been rejected in a minor organ transplantation case In Re Guardianship of Pescinski (1975) 67 Wis 2d 4 226 NW 2d 180. Clearly, what the incompetent would have done if competent is just one factor in the overall determination of best interests. It has been stated in the Massachusetts jurisdiction, where most of the US decisions relating to organ donation by incompetent donors have been made, that,

"the justices have not clearly articulated the legal theory upon which their decrees have been based"<sup>55</sup>

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<sup>54</sup>In Re J (a minor) (wardship: medical treatment) (1991) Fam 33 substituted judgment was applied to a neonate but generally the doctrine has lost favour and is only one of several factors that may be taken into account within the overarching context of the minor's best interests. This approach is also the Law Commission's recommended one for adults.

<sup>55</sup>Live Organ and Tissue Transplants from Minor Donors in Massachusetts, *Boston U Law Review* 1975, 55, 159 at p169.



However, it is clear, as Justice Calvo states in Curran v Bosze,<sup>56</sup> that there is only one *test* in the case of a minor who is unable to give informed consent (and this generally applies in the US),

“notwithstanding the language used by the courts in reaching their determination that a transplant may or may not occur, the standard by which the determination was made was whether the transplant would be in the best interest of the child or incompetent person.”

In English law there has been a brief dalliance with the notion that a procedure might be justified where it *was not against the child's best interests* (per Lord Reid in S v S [1970] 3 All ER 107 (HL) in the case of a simple blood procedure)<sup>57</sup> but this approach has never gained currency in subsequent cases including the bone marrow donation case of Re Y. On principle it is also a controversial approach that invades children's rights and autonomy on the basis of medically (and possibly judicially) conceived notions of utility.

#### Conditions For Accepting Living Organ Donation By Incompetent Minors Under the Best Interests Test.

The strict answer is that the best interests test has only one condition; showing that the proposed decision is in the best interests of the incompetent. However, donation by incompetent minors has traditionally been authorised in US cases where a combination (or all) of the following are present:

- contended 'extraordinary benefits' to the recipient from the proposed transplant;
- the minimal risks to the donor;
- the consent of the parents *and*
- the agreement of the minor donor (not necessarily mature agreement e.g. in Hart v Brown donation between 7 year old identical twins was found acceptable.<sup>58</sup>

There has also been attempts in individual US cases to elucidate the conditions that should be met for a donation to be declared in the best interests of the incompetent minor. In Curran v Bosze<sup>59</sup> the proposed testing of three and a half year old twins for possible

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<sup>56</sup>(1990) 566 NE 2d 1319 (Illinois Sup Ct).

<sup>57</sup>[1970] 3 All ER 107 at 110.

<sup>58</sup>29 Conn. Supp. 368, 289 A.2d 386 (Super Ct 1972).

<sup>59</sup>(1990) 566 NE 2d 1319 (Illinois Sup Ct).



bone marrow donation to a half sibling who they had only met on two occasions. The court refused to grant a petition for testing and thus the petition that they be used as organ donors if compatible was also ruled out. Mr Justice Calvo's suggested 3 criteria must be satisfied to declare an organ donation as in an incompetent minor's best interests:<sup>60</sup>

1. the parent or guardian who consents on behalf of the child must be informed of the risks and benefits inherent in the procedure;
2. There must be emotional support available from the person or persons who take care of the child; *and*
3. there must be an existing close relationship between the donor and the recipient. The reason behind this was the need for psychological benefit to be present not just in the form of altruism but in terms of the possible consequences for the particular donor given the particular relationship.

The second criteria was not met in the immediate case, because the day to day carer of the twins was not in support of the procedure. Nor was the third, because the twins did not know their half sibling to any significant degree.

English law only has Re Y<sup>61</sup> - a bone marrow donation by an incompetent adult - to offer guidance. The commentary on Re Y suggested that even in bone marrow cases the courts will look for evidence of a close relationship which will be damaged if the donee-patient dies and added that it was unlikely the court would contemplate even a minimally risky procedure with a child if the child's age prevented him her forming such a relationship with the donee-patient.<sup>62</sup> However, there was not a fundamental and vital connection between the incompetent and prospective recipient in the case itself which in the end was probably partly sanctioned on grounds of utility to the recipient combined with the low detriment in bone marrow donation.

#### Limitations of the Best Interests Test in the Field of Living Organ Donation by Incompetent Minors.

Under best interests, although substituted judgement is relevant, the minor's known values and views are not decisive and can be overridden. Use of the test can thus *impose*

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<sup>60</sup>(1990) 566 NE 2d 1319 (Illinois Sup Ct).

<sup>61</sup>Re Y commentary [1996] Med L Rev 205-207.

<sup>62</sup>Re Y commentary [1996] Med L Rev 205-207 at 206.



a decision upon a minor, as was the case in Re W itself. However, the test does at least somewhat protect against extreme utilitarianism by the fact that benefit to another *cannot* be used directly as a justification for medical intervention.

In living donation, since the minor can accrue no physical benefit from donation, intervention under the best interests test should at least be founded on a minimum of *physical detriment being outweighed by psychological benefit or freedom from psychological detriment*. Studies on the psychological impact of donation to minors indicate a very positive picture of benefit. Bernstein and Simmons have concluded that older minor donors tend to gain significant psychological benefits such as increased self esteem (more so than the average adult).<sup>63</sup> Simmons et al., have emphasised positive attitudes amongst teenage donors and that problems with this group are no more common than with adult donors.<sup>64</sup> Lewis suggests that even younger donors may gain similar benefits though he recognises that this is somewhat uncertain.<sup>65</sup>

'Psychological benefit' is sometimes used to suggest the risk is well worth the potential donor taking in return for the likelihood of a well recipient, a point especially stressed where the recipient is likely to have long life with the new organ.<sup>66</sup> Some commentators have gone further and even argued that even when it is adults who refuse to let a young person be a donor that young potential donor may subsequently feel a personal responsibility for the refusal.<sup>67</sup>

However, there are serious problems in taking psychological factors into account in incapacitate minor organ donation. Using psychological assessments to justify donation by an incompetent is *speculative in individual cases*. As a matter of evidence should

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<sup>63</sup>Bernstein & Simmons, The Adolescent Kidney Donor: The Right To Give, *Am.J.Psychiat*, 1974, 131, 1338, 1340.

<sup>64</sup>One of the major ethical controversies has involved the use of teenage donors. The question is whether such young people are capable of informed consent. At the University of Minnesota 18 donors from age 16-21 were used and evaluated. There was no more evidence of blatant family pressure in this group than in the other age groups, and there was only one donor who showed long-term ambivalence about the donation. In general the adolescent kidney donors indicated highly positive attitudes toward the donation and improvement in the self-picture afterward. Gift of Life at 431-3

<sup>65</sup>Lewis, Kidney Donation by a 7 Year Old Identical Twin Child: Psychological, Legal and Ethical Considerations, *J. Am. Acad. Child Psychiat*, 1974, 13, 221 at 228-232.

<sup>66</sup>Madsen v Harrison, Mass Supreme Judicial Court, Equity No. 68651, June 12, 1957. See also Lewis *ibid*.

<sup>67</sup>This was the view expressed by Shalom Schwartz, Professor of Sociology, University of Wisconsin, Madison, Dec 13, 1974 in a telephone conversation with Charles C Baron (See Baron, Live Organ and Tissue Transplants From Minor Donors in Massachusetts, *Boston U Law Review*, 1975, 55, 159



there be a minimum degree of certainty of psychological benefit to warrant the intervention in order to avoid decisions being too heavily founded on recipient benefit? Certainly US decisions involving minors under 8<sup>68</sup> appear to be a 'utilitarian infringement of rights' given there is little concrete evidence with which to determine whether the *particular minor at hand* will benefit psychologically.<sup>69</sup>

The fact that Simmons et al., found that 43% of family relatives of potential recipients did not go ahead and have the initial blood test,<sup>70</sup> and in general about 30% of adults have objections to transplantation, is evidence that psychological benefit in incompetent minor donation is uncertain. 'Negative' responses could include feeling wrongfully invaded as well as simply disagreeing with the idea of donation. Such negative responses must be taken seriously - indeed they can preclude or reduce psychological benefit in a given case.<sup>71</sup>

### 7.2.1.3. Conclusion

Without the security of the minor's consent, donations can always be covertly based on considerations of recipient benefit - it is difficult to escape the conclusion that the US decisions sanctioning use of exceptionally young minors have been so based.<sup>72</sup> The seriousness of donation and the scope for intra-familial conflicts of motivation give rise to pressures that may subtly, situationally or more overtly 'manufacture' a child's assent to donation which then becomes a justification for intervention.<sup>73</sup>

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<sup>68</sup>E.g. *Hart v Brown* 289 2 Ad 386 (1972) and also donation of skin to an identical 3 year old brother upheld by a Washington Court (see P.Herron and I.Marion, *Homografting in The Treatment of Sever Burns, Pacific Med and Surg*, 1967, 75, 4.

<sup>69</sup>For criticisms see Hollenberg NK, *Altruism and Coercion: Should Children Serve as Kidney Donors*, *N Engl J Med*, 1977; 296: 390. See also W.J.Curran WJ, *Kidney Transplantation in Identical Twin Minors: Justice is done in Connecticut*. *N Engl J Med*, 1972, 287, 26. For an article taking a more favourable approach to donation by young minors see Lewis, *Kidney Donation by a 7 Year Old Identical Twin Child: Psychological, Legal and Ethical Considerations*, *J. Am. Acad. Child Psychiat*, 1974, 13, 221 at 228-232. Where specific evidence is present that the minor will not benefit US courts have recognised this (see e.g. *Camitta v Fager*, Eq. No. 73-171 (Mass., Sept 5, 1973) where the prospective donor's guardian ad litem contended that the minor donor's mental state characterised as a combination of mild retardation and schizophrenia precluded realisation of any psychological benefits.

<sup>70</sup>*Gift of Life*, *Wiley and Sons*, 1977 at 431-3.

<sup>71</sup>This area of motivations is discussed further in chapter 6.

<sup>72</sup>E.g. *Hart v Brown* 289 2 Ad 386 (1972) and also donation of skin to an identical 3 year old brother upheld by a Washington Court (see P.Herron and I.Marion, *Homografting in The Treatment of Sever Burns, Pacific Med and Surg*, 1967, 75, 4. See Hollenberg NK, *Altruism and Coercion: Should Children Serve as Kidney Donors*, *N Engl J Med*, 1977; 296: 390.

<sup>73</sup>Including family conflicts. The feeling of guilt and / or family disapproval that can be the feared and / or actual consequence of not donating can be one factor in assuring assent. In one study an adult offspring



Substituted judgement provides some protection through the decision being based on 'patients' known values and feelings.' Robertson has advocated the general application of substituted judgement to cases of organ donation by incompetents for a number of reasons including the notion that it attempts to continue regarding the incompetent person,

"as an individual with free choice and moral dignity, and not as someone whose preferences no longer mattered."<sup>74</sup>

However, McLean has pointed out that where a person has always lacked capacity,

"what he or she would do if competent is simply a matter of speculation."<sup>75</sup>

The test could be limited to situations in which something is genuinely known about how the minor may have decided. For example, where the minor is only temporarily incompetent and previously expressed his / her views (as in Pescinski<sup>76</sup> and in Re W<sup>77</sup>) or permanently incapacitated and has done so. If best interests is to be used in organ donation it ought to be confined to situations where use of substituted judgement is sophistic. In general allowing organ donation by an incompetent minor should really be something out of the ordinary, perhaps necessitating:

- the minor exhibiting some kind of meaningful agreement to the proposed donation<sup>78</sup>  
*and*

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donor ran away the day before the operation after agreeing to donate, suggesting he was not so happy about the idea but had felt pressure to donate (R.G.Simmons et al., *Donors and Non Donors: The Role of the Family and The Physician in Kidney Transplantation* in Land and Dossetor (eds). *Organ Replacement Therapy: Ethics, Justice and Commerce*, Springer Verlag, 1991 at p108). Assent may be influenced by the fact that donation is sometimes seen as an aid to being seen as more mature rather than childish (For 6 out of 26 adolescent donors in the Minnesota study of 114 donors - see R.G.Simmons et al., *Gift of Life*, Wiley and Sons, 1977, 177). In some cultural sub groups (e.g. some Asian cultures) vulnerability to compulsive assent may arise through norms of family reciprocation applying to offspring.

<sup>74</sup>Organ Donation by Incompetents and the Substituted Judgement Doctrine, *Columbia LR*, 1976, 76, 48.

<sup>75</sup>McLean, *A Patients Right to Know*, Dartmouth Publishing, 1989 at p68.

<sup>76</sup>While he was not classified as incompetent before this he may have been, however.

<sup>77</sup>Where consent to treatment on behalf of an anorexic minor was at issue. See Kennedy and Grubb *Medical Law, Text with Materials*, Butterworths, 1994 at p289. For an example of where substituted judgment was used see Re Lucille Boyd [1979] 403 A 2d 744 (Dc Cir) where the pre-incompetency religious beliefs of the incompetent person suggested that she would have refused treatment.

<sup>78</sup>Suggested as a rule of thumb even for bone marrow donation in the Re Y commentary, *Med L Rev* 205-207 at 207 - the case and commentary is discussed further in section 7.4.



- the prospective recipient is in clinically urgent need of an organ and there is no prospect of a reasonable cadaver option turning-up within a time frame that will avoid significant jeopardy or actual harm to the prospective recipient; *or*
- the recipients survival or health being exceptionally linked to a need for a living donation or a very high quality organ match that only the incapacitate can provide<sup>79</sup> *and*
- the prospective recipient being an integral part of the incompetents existence in such a way that the incompetent has a tangible direct interest in helping the prospective recipient maintain / regain health.

A problem in justifying incompetent minor organ donation today is that there will usually be a reasonable alternative - for instance, in kidney donation, waiting for a cadaveric organ will often represent a reasonable alternative.

### **7.2.2. Competent Minors and Living Organ Donation.**

#### **7.2.2.1. When Does Minor Competence to Donate an Organ Exist?**

In examining general principles of law judges have expressed some pessimistic views about whether a minor could be competent to donate organs. For instance, Lord Donaldson in Re W went as far as to doubt whether a minor (an under 18 in this instance) would ever be Gillick competent to be a living organ donor<sup>80</sup> a view echoed recently in the case commentary of Re Y (Adult Incompetent: Legality of Non-Therapeutic Procedure) [1996] Med L Rev 204-205,

“given the need to weigh the benefit of the procedure against the risks of doing it, it is not likely that a court would contemplate donation of non-regenerative tissue such as a kidney (by a minor).”<sup>81</sup>

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<sup>79</sup>Of the Irish cohort of donor-recipient pairs interviewed (see chapter 8) one pair had been 13 year old twin sisters at the time of donation. David Price and I spoke retrospectively with the President of the Irish High Court about this donation and he expressed no objections. The donor agreed to the procedure but it was uncertain whether she was able to give fully informed consent, however the organ had an expected graft survival of 37 years - approximately 4 times the average cadaveric graft survival. The donor and recipient were also very close. Even so this donation would not have met the exceptional criteria noted above because there was no exceptional need.

<sup>80</sup>[1992] 3 WLR 758 at 767F. He felt that persons under the age of 18 could quite possibly be competent to donate blood.

<sup>81</sup>[1996] Med L Rev 205-207 at 206.



There are, of course, different decision-making processes in children to those adopted by adults. Piaget suggests that younger children are in a preoperational cognitive stage of development<sup>82</sup> a point expanded on by Kohlberg in his cognitive developmental theory.<sup>83</sup> However, evidence regarding younger children should not be taken to mean that all minors are likely to be too immature to donate. In reviewing psychological studies of minor decision-making David Price and I<sup>84</sup> concluded that,

"studies of intellectual development suggest that from 7-8 years the child is capable of certain logical reasoning processes applied to concrete objects or events in the immediate present. From 11-15 years the ability to reason hypothetically is also formed."

This paper noted that hypothetical reasoning is an intrinsic aspect of the organ donation decision-making process. Is hypothetical reasoning sufficient however? Clearly a minor might have hypothetical reasoning but not have sufficient maturity and understanding to reasonably apply that to their own situation. Theoretically a minor between ages 11 and 15 *could* be competent to donate an organ but this is likely to be very rare. However, in a world where teenagers make many important decisions, including marriage, it does seem unduly pessimistic to suggest that persons under 18 are unlikely to ever have capacity to donate an organ; several US decisions including Masden v Harrison<sup>85</sup> (14 year old) and Rappeport v Stott<sup>86</sup> (17 year old) have held otherwise. Surely teenagers in England and Wales are not any more immature than those in the US?

#### **7.2.2.2. The Competent Minors Liberty to Donate.**

##### **Is Competence of Itself Sufficient for a Minor's Choice to be Determinative?**

Whilst teenagers are in a vulnerable zone between childhood and adulthood<sup>87</sup> it is difficult to justify limiting their autonomy by imposing conditions on their donating over

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<sup>82</sup>J.Piaget and B.Inhelder, *The Psychology of A Child*, *Basic Books*, 1969.

<sup>83</sup>L.Kohlberg, *Stage and Sequence: The Cognitive-developmental Approach to Socialization*. In A.Goslin (Ed) *Handbook of Socialization Theory and Research*, *Rand McNally*, 1969.

<sup>84</sup>See D.Price and A.Garwood-Gowers, *Transplantation From Minors Are Children Other People's Medicine*, *Contemporary Issues in Law*, 1995, 1(1), 1-25.

<sup>85</sup>Eq. No 68651 (Mass, June 12,1957). Confirmed in the same year by Huskey v Harrison Eq. No. 68666 (Mass., Aug. 30 1957) and Foster v Harrison Eq. No. 68674 (Mass., Nov. 20, 1957).

<sup>86</sup>Civil No.1. 74-57 (Mass, Aug 28, 1974).

<sup>87</sup>See Rappeport v Stott Civil No. 1. 74-57 (Mass, Aug 28, 1974).



and above those applying to adults in cases where they are competent. However, within some transplant laws, including Algeria,<sup>88</sup> the law governing the new Landers of Germany,<sup>89</sup> Greece,<sup>90</sup> Hong Kong,<sup>91</sup> India,<sup>92</sup> Lebanon,<sup>93</sup> Panama,<sup>94</sup> Mexico,<sup>95</sup> Spain<sup>96</sup> and Tunisia,<sup>97</sup> the use of minors as living organ donors has been excluded altogether. While such exclusion generates certainty it is at the cost of missing the opportunity to utilise capacitate minors some of whom may be just as mature and acceptable as donors as an average adult.

WHO Guiding Principle 5 excludes use of organ donors expressly.<sup>98</sup> It states that exceptions “may be made under national law in the case of regenerative tissue.”<sup>99</sup> Some transplant legislation regimes allow donation of tissues only<sup>100</sup> (e.g. The Netherlands,<sup>101</sup>

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<sup>88</sup>Law No. 85-05 of 16 Feb 1985 On Health Protection and Promotion (*Journal Officiel de la Republique Algerienne Democratique et Populaire*, 1985 (17 Feb), 8, 122-140.) section 163.

<sup>89</sup>Section 7(2) applicable to the 4 Landers of Unified Germany that used to form East Germany.

<sup>90</sup>Section 5 of Law Number 1383 of 2nd August 1983. Though note that under this law bone marrow may be exceptionally removed from a minor provided that she and the recipient are siblings they are fully histocompatible and consent has been obtained from the person legally responsible for her.

<sup>91</sup>Ordinance No. 16 of 1995 at section 5(4)b excludes minor under 16 from donating and only allows those 16-18 to donate if they are married. This provision may be though to unfairly discriminate against single and cohabiting 16-17 year olds.

<sup>92</sup>The Transplantation of Human Organs Act 1994 at section 2(f). See Organ Donation Consanguinity Vs Universality An Analysis of Indian Law at p4. Manuscript to be published in Transplantation Proceedings, December 1996 and can be obtained from EUROTOLD. Organs can be removed from deceased minors with parental consent (section 3(7)).

<sup>93</sup>Decree No. 109 of 16 September 1983 On the Removal of Human Tissues and Organs For Therapeutic and Scientific Purposes section 1(1).

<sup>94</sup>Law No. 10 of 11th July 1983 Regulating The Transplantation of Organs and Anatomical Parts and laying Down Other Provisions at s22. See also section 3 of the Draft Law of The Republic of Belarus On The Donation and Transplantation of Human Organs and Tissues. Argentina excluded minors under section 13 of Law No. 21541 of 21 March 1977 On the Removal and Transplantation of Organs and Anatomical Materials (Buenos Aires, Ministry of Social Welfare, 1977, 15pp). However this law has been repealed and replaced by a 1993 law the full text of which does not appear in the International Digest of Health Legislation.

<sup>95</sup>Federal Regulation of 16 Aug 1976 on use of human organs tissues and cadavers, (*Salud Publica de Mexico*, 1977, 19, 59-68) section 24.

<sup>96</sup>Section 2 of the Crown Decree of 1980.

<sup>97</sup>Law No.91-22 of 25 March 1991 On The Removal and Transplantation of Human Organs at section 2.

<sup>98</sup>“No organ should be removed from the body of a living minor for the purpose of transplantation.” See Human Organ Transplantation: A Report Under the Auspices of WHO (1987-1991) World Health Organisation, Geneva 1991/

<sup>99</sup>*Ibid.*

<sup>100</sup>Consent in such cases will be given on behalf of the minor - although in some instances the minor's view on the donation will be relevant and refusal or objection respected e.g. in laws of France, The Netherlands (Section 8(4) of the law. Hans Akveld in personal communication with the EUROTOLD project.), Belgium and Portugal (section 8(4) of 1993 law).

<sup>101</sup>The Netherlands Law of 24 May 1996. Non-regenerable body material can be donated (body material is all called organs under this law). Section 5(1) states that, “the removal of an organ from from a living



Belgium,<sup>102</sup> Slovenia,<sup>103</sup> Portugal,<sup>104</sup> Sri Lanka<sup>105</sup> and Zimbabwe<sup>106</sup> and for specific tissues only Romania,<sup>107</sup> Poland,<sup>108</sup> France,<sup>109</sup> Russian Federation<sup>110</sup> and Greece<sup>111</sup>).

US cases have the appearance of being somewhat contradictory as to the conditions necessary to allow living organ donation by competent minors. In Masden v Harrison<sup>112</sup> it was stated that a 14 year old minor accepted for donation had given informed and voluntary consent but not made clear if this was sufficient justification in itself for donation. In Rappeport v Stott<sup>113</sup> the Massachusetts Supreme Judicial Court upheld a minor's donation of bone marrow on the express ground that the 17 year old donor was,

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minor 12 or more years of age may be performed only if the organ concerned is regenerable, if the removal will not have lasting effects on the donor's health, and only for the purposes of transplantation into a blood relative, up to and including the second degree of relationship, who is in danger of losing his life, where such danger may not be readily as averted in any other way. Removal may not be performed until the minor has given his consent and consent has been obtained from the parents exercising parental authority or the guardian, as well as from the judge of the children's court." Section 5(2) deals with minor under 12 years of age and those 12 years of age or older and who is not capable of making a reasonable assessment of their interests in the matter of donation it makes the same stipulations as the above section but adds that the donor must attach "considerable importance to averting the danger of death threatening the blood relative concerned."

<sup>102</sup>Law of 1986 sections 5-7.

<sup>103</sup>Law of 1996 Article 11.

<sup>104</sup>Law of 1993 at section 8(4).

<sup>105</sup>The Transplantation of Human Tissues Act, No. 48 of 1987 at sections 7 and 8.

<sup>106</sup>Anatomical Donations and Post Mortem Examinations Act No. 34 of 1976 at section 12 particularly subsection (b).

<sup>107</sup>To a sibling only - *ibid* at Article 5(1). Article 5(2) requires authorisation to be given by those with legal custody in the presence of the president of the court or of a magistrate authorised by him. Article 5(4) adds that minor refusal to donate is a bar to harvesting.

<sup>108</sup>To an ascendant, descendant or sibling. There must be a direct danger of loss of life to the recipient or possibility to avoid such danger in a manner other than the transplant. The transplant must not cause any foreseeable deterioration of the proficiency of the donor's organism and the legal representative and custodial court appropriate to the donor's place of residence must give consent. The permission of minors over the age of 13 is also required. See Articles 9(2), 9(3) and 9(4) of the Law of 26 October 1995.

<sup>109</sup>Only on behalf of a sibling where consent has been given by each person exercising parental authority or the minor's legal representative expressed before the Presiding Judge of the *tribunal de grande instance* or the judge designated by him. "Authorisation must also be granted by a committee of experts who must ensure that the minor has been informed of the intended removal, so that he may express his wishes if he is capable of doing so. Removal shall not be carried out if the minor refuses." Article L 671-4 and 671-5 of Law No. 94-654 of 29 July 1994 On The Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation, and Prenatal Diagnosis. The composition of the committee of experts is laid down in Article L. 671-6 (See *IDHL*, 1994, 45(1), 473-482 at 475).

<sup>110</sup>Regulation 3 of 1992 law.

<sup>111</sup>Section 5 of Law No. 1383 of 2nd August 1983. Removal of bone marrow must be exceptional where the potential minor donor and recipient are siblings, are fully histocompatible and consent has been obtained from the person legally responsible for her.

<sup>112</sup>Eq. No 68651 (Mass, June 12, 1957). Confirmed in the same year by Huskey v Harrison Eq. No. 68666 (Mass., Aug. 30 1957) and Foster v Harrison Eq. No. 68674 (Mass., Nov. 20, 1957).

<sup>113</sup>Civil No.1. 74-57 (Mass, Aug 28, 1974).



"capable of consenting to the proposed procedure." This approach has been repeated with a sibling kidney donation in another jurisdiction.<sup>114</sup> However, in this latter case the judges could also point to clear psychological benefit to the donor. Indeed, it may be speculated in general, that to legally donate an organ a competent minor must evidence benefit (even if only required to evidence actual best interests if incompetent) through factors like a close pre-existing relationship with the prospective recipient. This restriction is likely to be founded on the grounds of the seriousness of the procedure, the fact that it is not designed for the therapeutic benefit of the minor and the connected point that there are potential conflicts of interest.

The danger of veto of a competent minor's choice is much more real than the danger of forced donation. Re W has reaffirmed the Gillick concept that parents have no right of veto if a doctor chooses to accept a capacitate minors choice.<sup>115</sup> However, there is no obligation on the doctor to accept the wishes of the minor rather than those of the parents even if he considers the former's approach more rational. Doctors might be reluctant to ever proceed without parental consent - through both conservatism and the shadows of doubt about the possibility of minor competency to donate that Re W have cast over the arena of LDT. Interestingly the US case of Bonner v Moran 126 F.2d 121 (1941)<sup>116</sup> goes as far as to suggest that parental consent *would* generally be required.<sup>117</sup>

### The Competent Minor's Right not to Donate

Inroads into the autonomy of the competent minor are very strong in English law with regard to medical treatment as a whole. Re W<sup>118</sup> (confirmed in Re R) has established that a competent minor can have his/her self-determination infringed without legal recourse *providing* the medical practitioner obtains a consent from someone who is in a position to legally consent on that minor's behalf (usually a parent/legal guardian).<sup>119</sup> Obtaining such a consent, according to Lord Donaldson's idiosyncratic judgement, acts as an insulating 'flak jacket' against legal liability *even where going against the view of a*

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<sup>114</sup>In the Alabama jurisdiction from a 17 year old donor to a 16 year old recipient - see G.Smitherson, The Legal Dilemma of Minor Sibling Kidney Donation, *The Alabama Journal of Medical Sciences*, 1982, 19(3), 309.

<sup>115</sup>[1992] 3 WLR 758 at 767 F.

<sup>116</sup>The US Court of Appeals for the District of Columbia.

<sup>117</sup>The case concerned a possible skin graft from the minor to his severely burned cousin. This case involved a minor without capacity but the principle stated in a manner general to minors.

<sup>118</sup>Re W (A Minor) (Medical Treatment) [1992] 3 WLR 758 (CA).

<sup>119</sup>*Ibid.*



*Gillick competent minor* (even if the minor is 16 or 17).<sup>120</sup> This approach runs counter to Hoggett's dictum that, "the capacity to consent must logically include the capacity to dissent"<sup>121</sup> and not surprisingly it has been stated that in English law, "..as far as teenagers are concerned there is no longer any *real* meaning to consent"<sup>122</sup>

Kennedy and Grubb suggest that Re W and Re R are "provocative;"<sup>123</sup> neglecting the most fundamental value in section 8 of the Family Law Reform Act - that of respecting autonomy.<sup>124</sup> They note the disturbing possibility that the decisions might allow a doctor to be immunised from liability when performing a sterilisation or abortion on a young competent woman without her consent.<sup>125</sup> Similarly disturbing and far more consequentialist is the theoretical possibility that organ and tissue removals with potentially serious consequences might be performed on unconsenting competent minors.

Since LDT is only intended to be a voluntary gifting act the spectre of forcing someone to donate should, and probably would, be ruled out at the earliest opportunity. Fortunately, Re W and Re R in general, and the assessment in some cases before Masden v Harrison that the consent of parents alone might be sufficient are all contentious, rejectable legal approaches, that are out of step with a modern approach in which the rights of older minors are treated seriously (most particularly of all in the context of living organ donation). Lord Donaldson's views conflict with the view of

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<sup>120</sup>Lord Donaldson stated that medical ethics would require a doctor to seek parental consent where a *Gillick* competent minor had consented to donation but *he did not consider this to be a legal duty* (Re W [1992] 3 WLR 758 at 767).

<sup>121</sup>Hoggett, B., *Parents, Children and Medical Treatment: The Legal Issues*, in P.Byrne (ed.), *Rights and Wrongs in Medicine*, *Kings Fund (OUP)*, 1986, 158.

<sup>122</sup>Jo Bridgman, *Old Enough to Know Best?*, *Journal of Legal Studies*, 1993, 13(1), 69.

<sup>123</sup>*Medical Law Text with Materials*, *Butterworths*, 1994, 393.

<sup>124</sup>*Medical Law*, *Butterworths*, 1994, 393. Section 8(1) of the Family Law Reform Act 1969 appears to treat 16 and 17 year olds as adults for the purposes of medical treatment: "(1) The consent of a minor who has attained the age of 16 years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his person, shall be as effective as it would be if he were of full age and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from parent or guardian." However in Re W section 8 was construed as 'not conferring' an absolute right of sovereignty in medical decision making to 16 and 17 year olds by virtue of subsection 3 stating that, "(n)othing in this section shall be construed as making ineffective any consent which would have been effective if this section had not been enacted." This was construed as insulating physicians from liability even where they were going against the wishes of a competent 16 or 17 year old minor provided that the consent of someone with legal authority to consent had been given. Clearly to gain prima-facie protection of the right to self-determination in medical treatment a person must be 18 years old. This decision appears to go against the spirit of *Gillick* which emphasised that the authority of adults progressively diminishes as the minor grows in maturity and understanding[1985] 3 All ER 402 - see Lord Scarman's speech particularly.

<sup>125</sup>*Medical Law Text with Materials*, *Butterworths*, 1994, 393.



Lord Scarman in Gillick and the policy of the Children Act 1989 under which a child who has sufficient understanding has a right to make an informed refusal to submit to a medical or psychiatric assessment or examination.<sup>126</sup>

Although, in their aim to protect doctors from liability, some of the recent decisions concerning minor decision making (including Re W and Re R) have extended state control over children and the family<sup>127</sup> it would be difficult to sustain donation as psychologically in the best interests of a minor opposed to it or even a minor who, although not opposing, had not given some active and meaningful agreement. This view is supported in Re W where Lord Donaldson implied that living donation cannot benefit a minor<sup>128</sup> while Lord Justice Balcombe more forthrightly ruled out the possibility of donation by an unconsenting competent minor. The case commentary in Re Y has even hypothesised that the court would, as a rule of thumb, look for agreement in *bone marrow* donation by an *incompetent* donor.<sup>129</sup> US minor donations have specifically been justified on the estimation that prospective psychological gains / avoidance of psychological harm brought about by donation outweigh prospective physical detriment. An English court might be influenced by this approach but only where the minor had no view or was in favour of donation; it would be hard to prove that a donor would psychologically benefit from a clinically unnecessary procedure (s)he is opposed to!

#### **7.2.2.3. Jurisdictions Only Allowing Competent Minors to Become Living Organ Donors.**

The transplant legislation of a number of jurisdictions including Poland,<sup>130</sup> Slovakia,<sup>131</sup> Cyprus,<sup>132</sup> Turkey,<sup>133</sup> Hungary,<sup>134</sup> Romania,<sup>135</sup> Ecuador,<sup>136</sup> Kuwait<sup>137</sup> and Bulgaria<sup>138</sup>

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<sup>126</sup> See sections 43(8), 44(7) and Schedule 3, paras 4(4) and 5(5).

<sup>127</sup> See Bainham, *The Judge and the Competent Minor*, *LQR*, 1992, 108, 194.

<sup>128</sup> Re W (A Minor) Medical Treatment [1992] 3 WLR 758 at 767F.

<sup>129</sup> Re Y commentary, *Med L Rev* 205-207 at 207 - the case and commentary is discussed further in section 7.4.

<sup>130</sup> Law of 26 October 1995 Regulating The Removal and Transplantation of Human Cells, Tissues and Organs at Article 9(1). See *Transplantation From Living Donors Who are Unable to Give Consent For Organ Harvesting*, Marek Safjan, Dorota Safjan. Manuscript to be published in *Transplantation Proceedings*, Dec 1996. Copies of this and the Law available from EUROTOLD.

<sup>131</sup> Section 46(1) of Law No. 277 of 24 August 1994.

<sup>132</sup> Law No. 97 of 1987 On The Removal and Transplantation of Biological Materials of Human Origin at section 7(3).

<sup>133</sup> States that, "the removal of an organ or tissue from a person under 18 years of age... shall be permissible in cases where the person has drawn up and signed a document in the presence of at least 2 witnesses and in the absence of any pressure of any kind, or where the person has given an oral undertaking in the presence



restrict living organ donation to capacitate minors.<sup>139</sup> Some jurisdictions indirectly arrive at the same result e.g. the requirement in Norway<sup>140</sup> and Denmark<sup>141</sup> that the minor consents to the removal is almost equivalent to the requirement for capacity because consent under these jurisdictions means understanding the risks, consequences etc.<sup>142</sup> Donations not classed as between genetic relatives under HOTA can only be conducted if the donor "understands the nature of the medical procedure and the risks, as explained by the registered general medical practitioner, and consents to the removal of the organ in question."<sup>143</sup> In effect 'non-genetic-relative' donation is almost limited to donors who are competent. Norway<sup>144</sup> and Denmark<sup>145</sup> require special reasons for donation; presumably justifications like closeness of donor-recipient relationship, quality of match, unusual need and lack of reasonable alternatives. Norway,<sup>146</sup> Denmark<sup>147</sup> and

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of at least two witnesses and has signed a declaration which is then countersigned by a physician." Donors under the age of 18 (as well as adults) are prohibited from donating if they are deemed "unable to take their own decision for mental or psychological reasons." This appears to be equivalent to a requirement for capacity. Section 6 of Law No. 2238 of 29 May 1979.

<sup>134</sup>Ordinance No.18 of 4 November 1972 of the Minister for Health for the Implementation of Law No. II on Health Relating to the Removal and Transplantation of Organs and Tissues states in section 51(2) that the physician performing the transplantation is responsible for informing the patient "*or, if he is a minor, his relative of the necessity of the operation, the risks it entails.. and that the written declaration of the relative indicating that he consented of his own free will and in the absence of any pressure, must be kept in the clinical file of the patient.*" However, the Ordinance Law No. 6 of 1987, amending the 1972 law, states in section 7(2) that, "in the case of transplantation of bone marrow, removal may also be carried out on the body of a minor, with the consent of his legal representative. In the case of the withdrawal of tissue from the body of a minor of limited competence, the donor's consent shall also be required." This section appears to refer to tissue but not organ donation by capacitate minor donors.

<sup>135</sup>Article 4(1) of the 1996 Law Regarding The Harvesting and The Transplantation of Human Tissues and Organs. Regulation 133. Also note that s129 even prohibits the donation of blood by minors.

<sup>136</sup>Law No. 64 of 26th May 1987 section 24.

<sup>137</sup>Decree-Law No. 55 of 20 December 1987 On Organ Transplantation section 2. Although one conceivable interpretation is that this section only applies to cadaveric even if it did in the statute it is hard to see living donation being interpreted less stringently in practice than cadaveric.

<sup>138</sup>Ordinance No 15 of The Minister of Public Health On the Transplantation of Human Organs, 30th April 1976 No. 35. Bulgaria's law is currently under review.

<sup>139</sup>See also Peruvian law which simply states that "the donor shall have given his express consent" which probably means a competent consent (Law No. 23415 of 1 June 1982 at section 7(b)) and Vietnam law - although in the case of the minor recipient relatives or guardians may consent which might mean they could also consent for the donor. Law of 30 June 1989 On The Protection of Public Health (section 30(2)).

<sup>140</sup>Law No. 6 of 19 Feb 1973.

<sup>141</sup>Law No. 402 of 13 June 1990 at section 13(2).

<sup>142</sup>See chapter 5.3. Norway's law (1973) states that the minor donor must have understood the information concerning the nature of the operation and its consequences which was provided to him by a physician.

<sup>143</sup>The Human Organ Transplants (Unrelated Persons) Regulations 1989 (SI No 2480) at regulation 3(1) b.

<sup>144</sup>Requires special grounds to exist (Law No. 6 of 19 Feb 1973).

<sup>145</sup>Requires that there are special reasons for performing the intervention on a person under the age of 18 (Law No. 402 of 13 June 1990 at section 13(2)).

<sup>146</sup>Requires the agreement of the minor's guardian and the person exercising parental authority and responsible for the care of the minor (Law No. 6 of 19 Feb 1973).



Bulgaria<sup>148</sup> impose the requirement of parental consent; making parental veto possible. Norways law<sup>149</sup> requires the approval / authorisation of a National Health Board.

### 7.2.3. Court Involvement.

The seriousness of minor organ donation and the conflicting interests involved<sup>150</sup> make the involvement of the courts, or a quasi-legal body, essential. This approach has typically been accepted in the US.<sup>151</sup> The approach of cases in the UK is more divided. Lord Donaldson in Re W seems to imply that court involvement would *not* be mandatory for organ donation at least where the doctor reasonably believes the minor is Gillick competent or obtains the consent of someone legally able to consent on behalf of the minor.<sup>152</sup> The furthest he went was to say that,

"a doctor may well be advised to apply to the court for guidance, as recommended by Lord Templeman in a different context in Re B (a minor)(wardship: sterilisation) [1988] A.C. 199, 205-6."<sup>153</sup>

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<sup>147</sup>Requires that the approval of the person exercising parental authority has been obtained (Law No. 402 of 13 June 1990 at section 13(2)).

<sup>148</sup>Law of 1996.

<sup>149</sup>Requires the agreement of the directorate of Health Services (Law No. 6 of 19 Feb 1973).

<sup>150</sup>The Law Commission also took the view that, "(r)efERENCE to a judicial forum can ensure that decisions are made properly, and are seen to be made properly, and protect those providing the treatment from criticism or future liability. In addition there may be a category of decisions which are so serious that the involvement of a judicial body is always required." (Law Commission's Consultation Paper on Mentally Incapacitated Adults and Decision Making: Medical Research and Treatment, No. 129 at 4.1.) If this is to apply to adults there is also a clear basis for it to apply to minors.

<sup>151</sup>Hart v Brown, 29 Conn. Supp. 368, 289 A.2d 386 (Super. Ct 1972); Howard v Fulton-DeKalb Memorial Hosp. Auth., Civil No. B-90430 (Super. Ct., Fulton County, Ga., Nov. 29, 1973); Children's Memorial Hosp. v. Lewis, No. 73CH6936 (Cir. Ct., Cook County, Ill., Nov. 21, 1973); In re Richardson, 284 So. 2d 185 (La. App. 1973); In re Bostrom, Eq. No. 49385 (Cir. Ct., Montgomery County, Md., June 7, 1974); In re Bachman, Fid. No. 20828 (Cir. Ct. Fairfax County, Va., Aug. 9, 1974); Lausier v Pescinski, No. 668 (Wis., Mar. 4, 1975). Washington is an exception - the Attorney General's Office appears to have determined that the written consent of the legal guardian is sufficient consent for a minor or other legal incompetent.

<sup>152</sup>[1992] 3 WLR 758 at 767. He stated that, "Organ transplants are quite different and, as a matter of law, doctors would have to secure the consent of someone with the rights to consent on behalf of a donor under the age of 18 or, if they relied on the consent of the minor himself, or herself, be satisfied that the minor was Gillick competent in the context of so serious a procedure which could not benefit the minor." Reversed around this statement means that however desirable court involvement might be with regard to minor donors it is not legally necessary as the doctors will be insulated from liability if they follow Donaldson's instructions.

<sup>153</sup>[1992] 3 WLR 758 at 767G.



Mr Justice Connell in Re Y merely suggested court involvement was appropriate in adult incompetent bone marrow cases.<sup>154</sup> David Price and I have suggested that Donaldson's approach to minors in Re W may *not* be good law.<sup>155</sup> Indeed, Lord Justice Nolan in Re W contradicts Donaldson's approach. He considered Court involvement to be mandatory in the context of a potential abortion procedure and added,

"I would say the same of a case in which a child of any age consented to donate an organ."<sup>156</sup>

This is consistent with the approach recommended by the Law Commission<sup>157</sup> for *adult* incompetent bone marrow and organ donation.<sup>158</sup>

#### **7.2.4. Conclusions Regarding Minors and LDT.**

The legislative approach to organ donation by minors has so far had an overriding emphasis on restricting minors to areas where the potential risks of donation are low, with the unwitting exception of often allowing liver segment donation. In a few

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<sup>154</sup>[1996] Med L Rev 204-205 at 205.

<sup>155</sup>Price and Garwood-Gowers, *Transplantation From Minors: Are Children Other People's Medicine, Contemporary Issues in Law*, 1996, 1(1), 1-27 at 17.

<sup>156</sup>Re W [1992] 3 WLR 758 at 782C.

<sup>157</sup>Law Com No. 231 at p85.

<sup>158</sup>Tissue donation can be distinguished given that it usually involves lesser detriment to a donor but ought (unless de minimus detriment at issue) to necessitate court involvement simply because of the conflicting interests involved, the fragile status of the prospective donor and the difficulties of assessing best interests where a non-therapeutic procedure is involved. In contraceptive sterilisation cases involving adult incapacity, views have varied amongst judges from seeing court involvement as mandatory (Lord Templeman in Re B (a minor) (wardship: sterilization) [1988] AC 199, Lord Griffiths in Re F (mental patient; sterilisation) [1990] 2 AC1 and the majority in the Australian case of Department of Health v JWB & SMB (1992) 66 ALJR 360 (Aust High Ct)) to merely seeing it as desirable (Lords Brandon and Goff in Re F [1990] 2 AC). The net effect of a series of recent lower court decisions by Sir Stephen-Brown P (Re E (a minor) (medical treatment) [1991] 7 BMLR 117 (Fam Div) and F v F [1991] 7 BMLR 135 (Fam Div) and Re SG (a minor) (1991) 6 BMLR 95 (Fam Div)) appears to be that the court will only necessarily involve itself in matters which are non-therapeutic. This would almost certainly include organ donation as well as the more obvious example of contraceptive sterilisation. In Re F [1990] 2 A.C. 1, Lord Bridge in the House of Lords (ibid at 52), along with Neill LJ (ibid at 33) and Lord Donaldson MR (ibid at 19) in the Court of Appeal, mentioned that an operation to allow *inter vivos* organ donation by an incapacitated adult required similar safeguards to contraceptive sterilisation - i.e. court involvement. Arguably, sterilisation is a much more serious procedure than organ donation - the former has an intrinsic and fundamental (restrictive?) influence on the way a person lives their life, the latter would only do so if it 'went wrong.' Nevertheless, there is good sense in requiring court involvement for adult organ donation as well as sterilisation especially given the need to safeguard against utilitarianism.



instances the justifications (such as close donor-recipient relationship,<sup>159</sup> direct interest of the donor in saving the recipient's life<sup>160</sup> and need of the recipient<sup>161</sup>) must be higher than average as well. Minors clearly have restricted freedom in the donation of organs but this fact also means they are legally insulated from the possibility of risky / harmful procedures (particularly important given concerns about pressure and unconscious motivation discussed in the last chapter) and the reputation of the medical enterprise is protected. However, the failure of many transplant laws to make a distinction between capacity and majority denies autonomy and is difficult to ethically justify simply via paternalism.

Although common law is *generally* framed to restrict medical liability and maximise clinical discretion rather than protect autonomy of competent or incompetent patients, minor living organ donors are in something of an *exceptional* position. This exceptional position has meant that the wishes of competent and incompetent minors are often seen to be taken account of; especially in the context of not mandating a minor to donate an organ but also in valuing a minors viewpoint about the prospective living donation when assessing whether or not there is sufficient justification for a donation to go ahead.

Globally speaking, however, both transplant legislation and general principles of law in this area are some distance from methodologically considering the role of minors in the living organ donation decision-making process. This role should involve *competent minors being treated on a par with competent adults*.<sup>162</sup> The age of majority, and hence the presumption of capacity to donate an organ, should apply from the age of 16, 17 or 18

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<sup>159</sup>E.g. Belgium's law of 1986 (regulation 7) states that the recipient must be a sibling, as do French (law of 1994 Article L. 671-4 and 671-5), Greek (law of 1983 section 5-6) and Romanian laws (Article 5(1) of 1996. Poland's law of 1995 (Article 9(1)-9(4)) allows incapacitate minor donors to donate only to a linear relative or sibling. Slovenian law of 1996 (Article 9) allows such persons to donate to the direct family unity only 5-6), The Netherlands law of 1996 states that donors of 12-18 years must be donating to a first or second degree relative.

<sup>160</sup>E.g. The Netherlands 1996 for regenerative tissues states that if the donor is less than 12 he/she must have her own interest in saving the recipients life (plus additional requirements applying to donors over 12 years)..

<sup>161</sup>E.g. The Netherlands law 1996 states that where the donor is 12-18 the recipient must be in danger of losing his / her life for the donation to be permitted. This applies to regenerative tissue - not regenerative cannot be donated by a minor in The Netherlands.

<sup>162</sup>Price and Garwood-Gowers in *Transplantation From Minors: Are Children Other People's Medicine* noted the grounds suggested by the Law Reform Commission of Canada in its Report on the Procurement and Transfer of Human Tissues and Organs (Working Paper 66, 1992) for prohibiting all forms of donation by minors but each of these was countered in the paper which concluded that "there are really no compelling arguments against allowing (competent) minors to donate even (paired) non-regenerable organs in certain circumstances."



- in line with the age at which young people are considered adult for the purposes of making most serious decisions. The position could be subject to social and cultural variations but it may be thought that in all cases majority in organ donation should be no more than 18 years of age.

Incompetent minors should only being sanctioned as organ donors where they *explicitly agree* and have sufficient understanding and maturity for this agreement to be a *meaningful choice*. In this context the acceptance of very young minors must be regarded as dubious. Living organ donors as young as 7 have been accepted in the US; it must be concluded that a person of this age would normally only have sufficient maturity and understanding to make a meaningful choice about very simple and low level risks of donation, such as donation of blood. The presence of hypothetical reasoning (normally appearing between the ages of 11-15) ought to be treated as a minimum condition for organ donation by a minor. A mere assent, or absence of refusal, should be treated as insufficient on the basis that it does not adequately protect minor autonomy. Several other requirements should be added in the context of an organ donation by an incompetent minor, including:

- consent to donation of someone qualified to consent on the incompetents behalf (e.g. a parent - this is a matter of saying that a person who is not fully competent needs another person to help protect their interest);
- the donation must be *very likely* to be psychologically beneficial. This should be evidenced by a significant relationship between the minor and prospective recipient whereby the minor will be likely to gain significant psychological value from donation and/or avoid the likelihood of significant detriment from not donating. The mere fact that donation is in general psychologically beneficial should be regarded as a speculative and insufficient basis for justifying donation; *and*
- Prospective benefit must outweigh prospective detriment - i.e. the donation must be in the best interests of the incompetent. Organ donation is a serious and invasive procedure not designed for the benefit of the minor so benefit ought to clearly and significantly outweigh detriment (this requirement is perhaps more important than in the case of tissue donation). In addition, detriment should be limited; it might be considered that kidney donation is the only acceptable form of organ donation by a minor.



The best approach would be to use a legal forum, set up by legislation, to examine all prospective donations according to the above principles.<sup>163</sup> The presence of such a forum would help to allay the concerns of those who believe that only competent minors should be allowed to become living organ donors.<sup>164</sup> Such a forum could use expert psychological evidence and where appropriate use a social worker to interview a child.<sup>165</sup> Statutory regulations could lay down guidelines for the forum from time to time - such as guidance about different forms of donation, to be altered in the light of advances in transplantation practice.

### **7.3. Non-Minority Based Capacity and LDT.**

Historically adult incompetents have been vulnerable to the vagaries of extreme utilitarianism, including the application of eugenics ideas in the US. Even today adult incompetents are vulnerable to the covert or unconscious judicial application of 'social interests' disguised as an assessment of best interests. Theoretically this will particularly be a danger in living organ donation, given it is not a procedure designed for the benefit of the incompetent. Justifying adult incompetent donation can be particularly difficult where the incompetent has reduced (or even nil) ability to accrue psychological benefits in terms of self-esteem etc. from donation. In such cases donation would have to be shown to be of overall benefit to the incompetent via helping him/her avoid a degree of psychological harm *outweighing* the physical detriment of donation. Making an assessment of psychological benefit compared to physical harm is, as we have seen, often difficult - not least because there is a degree of speculation involved when examining the likely psychological impact of LDT upon the donor.

Despite the difficulties of justifying living organ donation by an adult incompetent, or for that matter an older minor with a mental condition, it has been sanctioned in a number of the major US cases.<sup>166</sup> Under English law bone marrow donation by an incompetent

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<sup>163</sup>Price and Garwood-Gowers, *Transplantation From Minors: Are Children Other People's Medicine, Contemporary Issues in Law*, 1996, 1(1), 1-27 at 18.

<sup>164</sup>For instance, D.Daube has suggested that a minors consent would be a minimum ('Transplantation: Acceptability of Procedures and the Required Legal Sanctions,' in *Ethics In Medical Progress*, G.Wolstenholme and M.O'Connor (eds.), *Little Brown*, 1966, 188-201.

<sup>165</sup>L.Delaney has suggested that a social worker could be used (see *Law and the Altruistic Child in Medicine*, in D.Lockton (ed), *Children and the Law*, *Cavendish*, 1993, 39 at 42).

<sup>166</sup>See e.g. *Strunk v Strunk* 445 S.W. 2d 145 (ky. 1969), *Little v Little* (Tex Civ 1979) 576 SW 2d 493, In *Re Guardianship of Pescinski* (1975) 67 Wis 2d 4, 226 NW 2d 180 and In *Re Richardson* (La App 1973), 284 So 2d 185. Some cases involve older minors and some adults.



adult was sanctioned in Re Y. In addition some transplant laws allow for donation of organs by an incompetent adult and in a few instances are so radical as to not require any special conditions for it other than the obvious requirement that someone with legal authority to consent must consent on the behalf of the incompetents. At the other end of the spectrum there are transplant laws which exclude the possibility of living organ donation by incompetent adults and even in some cases are framed in such a way as to potentially act as a 'drag net' preventing donation by some competent adults.

### **7.3.1. Defining Capacity in Relation to Adults with a Mental Disability / Illness / Condition.**

There are several overall approaches in English common law to defining adult-related capacity. Bristow J in Chatterton v Gerson [1981] 1 All ER 257 stated that the patient was required to understand the nature of the procedure and its consequences in broad terms in order to give a legally valid consent.<sup>167</sup> In Re F [1990] 2 AC 1 the test was ability to understand the nature or purpose of an operation or treatment.<sup>168</sup> This approach is usually referred to as the functional or cognitive approach. In Re C<sup>169</sup> Thorpe J focused on the test developed by Dr Eastman as an expert witness in the case. Eastman analysed the decision-making process into 3 stages: (1) comprehending and retaining information; (2) believing it and (3) weighing it in balance to arrive at a choice. This approach could simply be interpreted as a more detailed explication of the 'understanding in broad terms' required in Chatterton v Gerson.<sup>170</sup> A definitive test in this area is elusive; hence the recommendation of the Law Commission, in its recent Command Paper on adult medical decision making and capacity, of;

"..a single piece of legislation to make new provision for people who lack mental capacity; and to confer new functions on local authorities in relation to people in need of care or protection."<sup>171</sup>

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<sup>167</sup>[1981] 1 All ER 257 at 265 see also Re T (Adult: Refusal of Treatment) [1992] 4 All E.R. 649.

<sup>168</sup>[1990] 2 AC 1 at 55 per Lord Brandon.

<sup>169</sup>*NLJ*, 1993, 143, 1642.

<sup>170</sup>Of indirect legal effect, but general interest here is the Mental Health Act Code of Practice (which came into force on November 1st 1993). The Code applies to both detained and informal patients and provides that an individual in order to have capacity must be able to: Understand what medical treatment is and that somebody has said that he needs it and why the treatment is being proposed; understand in broad terms the nature of the treatment; understand its principle benefits and risks; understand what will be the consequences of not receiving the proposed treatment and possess the capacity to make a choice.

<sup>171</sup>Law Com No 231, HMSO, 1995, 29.



The Commission recommended that legislation relating to adult incapacity should apply to people aged 16 and over,<sup>172</sup> with a presumption against lack of capacity<sup>173</sup> and a person being defined as without capacity at the material time if he or she is

- "(1) unable by reason of mental disability to make a decision on the matter in question, or
- (2) unable to communicate a decision on that matter because he or she is unconscious or for any other reason."<sup>174</sup>

It added that in terms of the retention of information,

"..a person should be regarded as unable to make a decision by reason of mental disability if the disability is such that, at the time when the decision needs to be made, he or she is unable to understand or retain the information relevant to the decision, including information about the reasonably foreseeable consequences of deciding one way or another or failing to make the decision."<sup>175</sup>

with the requirement for understanding and retaining information being viewed as met where a person is,

"..able to understand an explanation of that information in broad terms and simple language."<sup>176</sup>

Concerned that a person should not only be able to retain and understand information but utilise it in the decision-making process, the Commission recommended that,

"..a person should be regarded as unable to make a decision by reason of mental disability if the disability is such that, at the time when the decision needs to be made, he or she is unable to make a decision based on the information relevant to the decision, including information about the reasonably foreseeable consequences of deciding one way or another or failing to make the decision."<sup>177</sup>

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<sup>172</sup>Page 30 *ibid.*

<sup>173</sup>Page 32 *ibid.*

<sup>174</sup>Draft Bill, clause 2(1)) at page 37 *ibid.*

<sup>175</sup>Draft Bill, clause 2(2)(a).

<sup>176</sup>Draft Bill, clause 2(3) at page 39 *ibid.*

<sup>177</sup>Draft Bill, clause 2(2)(b ) at page 39 *ibid.* The Commission also produced a thoughtful recommendation on the communication of decisions; "..a person should not be regarded as unable to



Perhaps one of the dangers here would be that a judge or clinician could use deduction to say that because of the ‘imprudent’ way a person has decided they couldn’t reasonably be viewed as having made a decision based on the relevant information. Such an approach would obliterate any practical role for autonomy which must include the right to make decisions which others regard as irrational or bizarre. Hence, the Commission framed a recommendation stating that a person,

“..should not be regarded as unable to make a decision by reason of mental disability *merely* because he or she make a decision which would not be made by a person of ordinary prudence.”<sup>178</sup> (emphasis added).

The problem with this provision is the use of the word ‘merely’ which would suggest that a person’s choice could be relied upon heavily (provided not completely) to conclude (or deduce?) that they do not have capacity. The danger here is still one of the imposition of a fairly homogenous set or narrow band of values upon people making decisions. In practice it may even make people with unusual medical viewpoints more vulnerable to being ‘found’ incapacitate to make a decision simply because of the unconventionality of their view. Consequently the recommendation may not guard enough against unnecessary breaches of a person’s right to bodily control. In most situations this would not have ramifications for a living donor who would be regarded as making a ‘prudent’ or at least ‘normal’ decision whether or not (s)he chose to donate. However, it could have ramifications if the donor was wanting to donate an organ with very high risks (such as a Leicester donor discussed in chapter 9 who wanted to donate his second kidney). It could also have ramifications for a prospective recipient, who may for instance wish to follow an unconventional course of rejecting transplant and dialysis altogether to use naturopathic, holistic treatment.

However, in general, the Commissions approach can be welcomed as one that if adopted would bring a degree of certainty to English law in this area although inevitably there will always be some difficulties in applying provisions in the field of complex and rapidly evolving medical technologies of which LDT is a part.

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communicate his or her decision unless all practicable steps to enable him or her to do so have been taken without success.” (Draft Bill, clause 2(5)).

<sup>178</sup>Draft Bill, clause 2(4). Evidence to the Commission overwhelmingly supported the inclusion of an express recommendation guarding against capacity being judged by the choice made itself (page 39-40 *ibid*).



### 7.3.3. Jurisdictions Allowing the Donation of Organs and Tissues by Incompetent Adults.

As well as being possible under general legal principles, some transplant laws specifically state that an adult incompetent may become a donor. Not surprisingly, such donation is always subject to special conditions.

#### 7.3.3.1. Conditions on Living Organ Donation by Incompetent Adults Under Transplant Legislation.

The Council of Europe's Resolution (78)29<sup>179</sup> restricts donation to regenerative materials<sup>180</sup> and this must only be in exceptional cases and where the incompetent does not object<sup>181</sup> and consent has been given by the legal representative.<sup>182</sup> Theoretically, allowing donation of regenerative materials results in the possibility of incompetent adult, living liver segment donation, although it is difficult to see their ever being sufficiently exceptional circumstances to justify this.

In Hungary,<sup>183</sup> Colombia<sup>184</sup> and Malawi<sup>185</sup> the condition is merely consent by the donor's legal representative but other transplant laws with provision in this area are stricter. For instance, Swedish law<sup>186</sup> states that transplant operations may be performed on persons who are incapable of giving consent due to a mental disorder if the donor is related to the potential recipient, if it is not possible to obtain medically compatible biological material from another person, if it is not against the donor's wishes, if consent is given by the guardian or legal representative *and* if the National Board of Health and Welfare authorises it - for this to happen there must be special justifications and the support of the physician empowered to decide on the removal. Swedish law does not state what special reasons constitute - possible factors might include a close relationship between donor and recipient and/or the likelihood of tangible harm to the incompetent should the

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<sup>179</sup>On Harmonization of Legislation of Member States to Removal, Grafting and Transplantation of Human Substances. Adopted by the Committee of Ministers of the Council of Europe on 11 May 1978.

<sup>180</sup>Article 6(2).

<sup>181</sup>Article 6(1).

<sup>182</sup>Article 2.

<sup>183</sup>"the legal representative (curator), in the case of a patient who is mentally incompetent or is of diminished responsibility" (Law No. 18 of 4 November 1972 at section 13).

<sup>184</sup>Decree No. 1172 of 6 June 1989 at section 30.

<sup>185</sup>Anatomy Act No. 14 of 1990 at section 11(b).

<sup>186</sup>Law No. 831 of 8 June 1995 at section 8 (*IDHL*, 1996, 47(1), 28-30 at 29).



recipient die. The Canadian Uniform Human Tissue Donation Act 1990 requires an independent assessment to be made where such an incapacitate donation is proposed but clearly envisages the possibility.

The status of mentally ill/disabled incapacitate donation is uncertain in Finland; a psychiatrist gives an account of the mental condition of the donor and his suitability as a donor. It would appear that 'unsuitable' donors are excluded.<sup>187</sup> Since 'unsuitable' is defined by a psychiatrist its ambit is uncertain. It may in practice mean that anyone incapacitate to donate would be excluded. Effectively English law prevents non-genetically related incompetent adult organ donation and leaves the legality of organ donation by genetically related incompetents to be determined under general principles.<sup>188</sup>

### **7.3.3.2. Conditions on Living Organ Donation by Incompetent Adults Under General Principles of Law.**

#### **The Approach Within Which Conditions are Framed**

The 'best interests' test and the substituted judgement doctrine<sup>189</sup> have been the subject of much comment in cases involving consideration of living donation by incompetent adults. English law has rejected the substituted judgement doctrine in Re Y (Adult Incompetent: Legality of Non-Therapeutic Procedure) [1996] Med L Rev, 204-205 where Mr Justice Connell in the High Court of Justice, Family Division used the best interests test in determining the legality of an adult incompetent donating bone marrow to her sister.<sup>190</sup> As regards US cases involving living *organ* donation by adult incompetents, the Kentucky Court of Appeals considered substituted judgement in Strunk v Strunk 445 SW 2d 145 (Ky 1969)<sup>191</sup> but as stated in Little v Little (Tex Civ 1979), 576 SW 2d 493, Strunk was not based on substituted judgement,

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<sup>187</sup>Ordinance No. 724 of 23 August 1985 On The Removal of Human Organs and Tissues for Medical Purposes at section 2).

<sup>188</sup>As seen in the section on minors Under HOTA, non-genetically related organ donation by an incompetent person is unlikely to ever be authorised.

<sup>189</sup>Used as far back as 1816 with an adult incompetent in Ex parte Whitebread 35 Eng. Rep. 878 (Ch 1816).

<sup>190</sup>Page 204. The US bone marrow case of Curran v Bosze (1990) 566 N.E. 2d 1319 (Ill.Sup.Ct) was used as authority.

<sup>191</sup>The New York case of In The Matter of Willoughby, A Lunatic 11 Paige 257 (N.Y. 1844) provided authority that the substituted judgement doctrine applied in the US. For further discussion of the doctrine see Annot, 24 A.L.R. 3d 863 (1969).



"It is clear in transplant cases that courts, whether they use the term 'substituted judgement' or not, will consider the benefits to the donor as a basis for permitting an incompetent to donate an organ. Although in *Strunk* the Kentucky Court discussed the substituted judgement doctrine in some detail, the conclusion of the majority there was based on the benefits that the incompetent donor would derive, rather than on the theory that the incompetent would have consented to the transplant if he were competent. We adopt this approach."<sup>192</sup>

The probable legal position is that substituted judgement is one of the factors for the doctor to take into account, "in forming a clinical judgement as to what is in the best interests of the patient." (per Lord Donaldson MR in *Re T (adult: refusal of treatment)* [1992] 4 All ER 649(CA)). The weight of opinion<sup>193</sup> and common sense goes against Lord Goff's view in *Airedale NHS Trust v Bland* [1993] 1 All ER 821 that substituted judgement formed no part of English law in relation to incompetent adults.

The use of the best interests test has not been without criticism. Judge Samuel Steinfield giving the dissenting opinion in *Strunk* took the view that consent was the sole justification for donation.<sup>194</sup> He placed weight upon concerns that the issue raised thoughts of experimentation on human subjects reminiscent of 25 years ago,

"apparently because of my indelible recollection of a government which to the shame of it's citizens embarked upon a programme of genocide and experimentation with human bodies I have been more troubled in reaching a decision in this case than in any other."<sup>195</sup>

The merit of this lone view is that preventing incompetent persons from donating protects them from utilitarian abuse. Allowing such donation opens the door to ignoring - or not thoroughly exploring the wishes, values and involvement of the incompetent in the decision - a situation which happened in *Strunk v Strunk* itself with the whole emphasis

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<sup>192</sup>*Little* 576 SW 2d at 498.

<sup>193</sup>The approach in *Airedale* is criticised by Kennedy and Grubb *Medical Law, Text with Materials, Butterworths*, 1994, 289. The authors doubt whether Lord Goff in *Bland* was sound in his reliance on *Re F (mental patient: sterilisation)* [1990] 2AC 1 (HL) as authority for substituted judgment not applying in English law. Lord Mustill also criticised substituted judgment in *Bland* but his comments were more relevant to the specific case of a non-sentient patient. *Re J (a minor) (wardship: medical treatment)* [1990] All ER 930 makes it clear that the individual circumstances of the particular person at issue need to be taken into account in deciding what's in the her/his best interest.

<sup>194</sup>"The ability to fully understand and consent is a pre-requisite to the donation of a part of the human body" (445 S.W. 2d 145 (Ky. 1969) at 150).

<sup>195</sup>445 S.W. 2d 145 (Ky 1969) at p149.



being on a paternalistic evaluation by the psychiatrist of the level of the incompetents capabilities (e.g. through I.Q. and other tests) without a real attempt being made to try and facilitate the incompetent's expression of his true feelings about donation.<sup>196</sup>

### Conditions for Accepting Living Organ Donation by Adult Incompetent's Under the Best Interests Test.

In terms of the general position for incompetent adults, there is considerable uncertainty as to the exact meaning of the best interests test in English law. The House of Lords recently considered the question in the sterilisation case of Re F [1990] 2 A.C. 1. Lord Brandon took the view that a treatment would be in the patients best interests where it was carried out to save his life or ensure improvement / prevent deterioration in his physical or mental health.<sup>197</sup> Some academics suggested that Lord Brandon was confining best interests to medical factors.<sup>198</sup> Whether or not this was the case it is now clear that assessment of best interests can involve "more than a purely medical opinion."<sup>199</sup> Indeed Lord Keith, in Airedale NHS Trust v Bland [1993] 1 All ER 821, took the view that the sterilisation of the patient in Re F had been determined to be in her best interests "because her life would be fuller and more agreeable" through it.<sup>200</sup> It is notable that if Re F were confining the 'best interests' test to medical factors bone marrow donation would never have been sanctioned in Re Y because donation would not be medically necessary. Indeed adult incompetent donation of tissues and organs as a whole would be unlawful.<sup>201</sup>

So what are the relevant factors in determining best interests? Lord Donaldson's in the Court of Appeal in Re F suggested that doctors exercising a choice on behalf of a patient should apply the same principles as those which would be applied by a 'reasonable' adult

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<sup>196</sup>At p74-75 of the Transcript the psychiatric testimony states that Jerry understood that, "the operation would hurt and that he might have to be in hospital for two weeks." and at p76 continues "I believe he does understand that the giving of a kidney is a helpful act because of his brother's ill health." Jerry is not understanding the process and it's consequence or even actually assenting to something he doesn't understand.

<sup>197</sup>Ibid at 55.

<sup>198</sup>A.Grubb and D.Pearl, Sterilisation - Courts and Doctors as Decision Makers, *CLJ*, 1989, 380, 382; D.Morgan, *J.S.W.L.*, 1990, 204, p206.

<sup>199</sup>Re F ibid at 78 per Lord Goff.

<sup>200</sup>Airedale NHS Trust v Bland [1993] 2 W.L.R. 316 at 361 and [1993] 1 All ER 821 at 860.

<sup>201</sup>Indeed Kennedy and Grubb in arguing that Re F is confined to medical factors have suggested that, "removal of tissue from an incompetent adult for transplantation would be unlawful" (Medical Law: Text With Materials, *Butterworths*, 1994, 1087).



considering his own medical treatment.<sup>202</sup> The result of applying this to organ donation is speculative; some adults choose to donate but a significant minority of presumably reasonable adults do not. The particularities of being an incapacitate donor would surely warrant the use of a more definite and stringent test than this. The Law Commission's findings in this area are to be welcomed as a well reasoned set of principles that could provide a degree of certainty in the living donation context. In recommending use of the best interests concept the Commission stated that in deciding what is in a person's best interest regard should be had to:

“(1) the ascertainable past and present wishes and feelings of the person concerned, and the factors that person would consider if able to do so;

(2) the need to permit and encourage the person to participate or to improve his or her ability to participate, as fully as possible in anything done for and any decision affecting him or her;

(3) the views of other people whom it is appropriate and practicable to consult about the person's wishes and feelings and what would be in his or her best interests;

(4) whether the purpose for which any action or decision is required can be as effectively achieved in a manner less restrictive of the person's freedom of action (Draft Bill, clause 3(2)).”<sup>203</sup>

This main features of this approach are a notion of substituted judgement in point 1, an emphasis on participation in decision making in point 2, an emphasis on drawing widely on relevant sources of evidence in point 3 and, in point 4, an emphasis on taking the option least restrictive for the incompetent. In terms of living donation these principles might translate into taking the prospective donors known views and wishes during any period where (s)he was competent into account, an emphasis on the incompetents current views and wishes, drawing evidence from the incompetents family and other sources and finally using the least restrictive option might translate into not using the incompetent as a donor where there is a feasible alternative.

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<sup>202</sup>[1990] 2 A.C. 1, 18.

<sup>203</sup>Law Comm No 231 at 44-45.



More direct illumination of the relevant factors in determining best interests in living donation cases is found in the bone marrow case of Re Y. The three main principles developed in this case are that:

- donation must benefit the incompetent, to a degree outweighing detriment;
- benefit from the procedure to the prospective recipient is only relevant in so far as it serves the best interests of the incompetent; *and*
- benefit goes beyond the purely medical to include “emotional, psychological and social benefit.”<sup>204</sup> This could include the benefit derived from altruistic gifting.

In Re Y itself, the benefit was contended to be derived from the fact that if the incompetent did not donate his sister would die placing extra burden on her family and in particular her mother who was already ill and would have to face the death and look after the plaintiff’s daughter. The relevance of this in terms of the incompetent was mainly that she was close to her family and would be harmed by the fact that with the burden of a death they would cease or dramatically reduce visits to her (she was institutionalised).<sup>205</sup> The harm done would outweigh the small disadvantages of bone marrow donation.<sup>206</sup> Additionally she would benefit from the donation through the gratitude of her family.<sup>207</sup>

The evidence of benefit has rightly been described in the case commentary as “not..particularly strong”<sup>208</sup> The justifications may have been enough for bone marrow donation but should clearly be viewed as insufficient for organ donation - indeed Mr Justice Connell himself reigned in the significance of the criteria applied in Re Y by stating that the decision should not be considered,

“a useful precedent in cases where the surgery involved is more intrusive.”<sup>209</sup>

However, the three principles in Re Y can be seen as a useful complement to the aforementioned Law Commission approach.

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<sup>204</sup>Re Y [1996] Med L Rev 204-207 at 205.

<sup>205</sup>*Ibid* at 205.

<sup>206</sup>*Ibid*

<sup>207</sup>Commentary note - *ibid* at 206.

<sup>208</sup>*Ibid*.

<sup>209</sup>*Ibid*.



In the US, the conditions for authorising a living organ donation by an incompetent adult have been examined more extensively. Strunk v Strunk was the first case involving an incompetent adult to hinge on whether a living organ donation could be established as in the best interests of the incompetent. The Court of Appeals held, by a 4-3 decision, that it had the power to permit a kidney to be removed from a person deemed an incompetent ward of State upon the petition of his committee<sup>210</sup> for the purpose of being transplanted into his brother, who was 'dying' of a kidney disease on the basis that the donation was in the incompetents best interests. Some of the dissenting minority felt that evidence in the case was insufficient to "conclusively demonstrate" a "significant benefit" to the incompetent, but that if the evidence ever did rise to that "pinnacle" the transplant should be allowed.<sup>211</sup> The dissenters were also concerned by the testimony that a cadaver kidney could be used. The basis for the majority view was not clearly articulated but the central factors were:

- *Firstly*, psychological value<sup>212</sup> for the incompetent based on closeness of relationship with his brother, the prospective recipient, including evidence that the latter represented the former's main link outside of institutionalisation and that the continued close relationship was important to the rehabilitation and treatment of the incompetent;<sup>213</sup> *and*
- *Secondly*, although clinical necessity for the donation was not established it was clear that the incompetent was the only viable living donor<sup>214</sup> and that this option was clinically vastly superior in this case to an average cadaver.<sup>215</sup>

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<sup>210</sup>Which in this case was his mother.

<sup>211</sup> In the first instance decision the Franklin County Court stated that, "it would be psychologically beneficial and in the interests of the incompetent to donate the kidney." It authorised the Committee to consent on behalf of the donor. The Guardian ad Litem for Jerry had argued that the removal of Jerry's kidney would violate his right to be secure in his person, his right to due process, and his right to due protection under the law. The Committee turned these arguments on their head by saying that since the donation would be beneficial to Jerry it would be a violation of his constitutional rights not to go ahead. The Court accepted the latter view. The guardian ad litem appealed to the Franklin Circuit Court (where the decision was affirmed) and then to the Kentucky Court of Appeals.

<sup>212</sup>This was urged by the Commonwealth of Kentucky Department of Health which was custodian for the incompetent (see p113 transcript).

<sup>213</sup>Transcript of the case entitled 'In the matter of Jerry Strunk, an incompetent, Aug 19, 1969 at note 41 p13-14. The transcript is on file with Franklin County Court. See also Joe C Savage, *Kentucky Law Journal*, 1970, 58, 132.

<sup>214</sup>Medical testimony stated that other relatives had been tested and none of them were well enough matched to be living donors (see page 44 of the transcript).

<sup>215</sup>90% chance of graft survival after 2 years due to 'top quality match' between the brothers as distinct to 40% with a cadaver.



In subsequent US cases, judges have generally been more reluctant to sanction this form of donation. In In Re Richardson (La App 1973) 284 So 2d 185 the Louisiana Court of Appeal distinguished Strunk from the case before it which involved a 17 year old incompetent with a mental age of 3 or 4 whose parents were consenting to his being the donor to his sister:

"We find the facts in (Strunk), particularly the conclusion relative to the best interest of the incompetent, are not similar to the facts in the instant case and we also find that both the procedural and the substantive aspects of the majority opinion are not in accord with Louisiana law ... (which) is designed to protect and promote the ultimate best interest of a minor.... since our law affords the unqualified protection against intrusion (sic) into a comparatively mere property right, it is inconceivable to us that it affords less protection to a minor's right to be free in his person from bodily intrusion to the extent of the loss of an organ unless such loss be in the best interest of the minor. Of course that statement and our conclusion are restricted to the facts of the present case."<sup>216</sup>

The decisions in Richardson and Strunk are distinguishable for several reasons. The most substantial and convincing of these reasons is the fact that in Strunk the potential donor's main contact with the outside world was the potential recipient and the two had a very close relationship while in Richardson the donor was not as dependant on the recipient for contact.<sup>217</sup> Re Guardianship of Pescinski [1975], 67 Wis 2d 4, 226 NW 2d 180 is reconcilable with Strunk - donation being rejected in Pescinski on the basis that the 37 year old incompetent would derive no benefit from donating to his brother.<sup>218</sup>

Richardson<sup>219</sup> was basically the first US case to fully articulate the principles in this area, stating that to be justified this kind of procedure must be:

1. Urgent;

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<sup>216</sup>Richardson, 284 So 2d at 187.

<sup>217</sup>Closeness is also an important factor with non mentally disabled/ill minors - see earlier section particularly Curran v Bosze (1990) 566 NE 2d 1319 (Illinois Sup Ct).

<sup>218</sup>"an incompetent particularly should have his own interests protected. Certainly no advantage should be taken of him. In the absence of real consent on his part, and in a situation where no benefit to him has been established, we fail to find any authority for the county court, or this court, to approve this operation" (Pescinski, 67 Wis 2d at 8-9, 226 NW 2d at 182). Pescinski simply rejected donation on it's facts; "the exercise of judicial restraint under particular circumstances" (Supreme Court of Wisconsin in In Re Guardianship of Eberhardy (1981) 102 Wis 2d 539 at 565).

<sup>219</sup>Gullotta J at 188.



2. have no reasonable alternatives; *and*
3. have minimal contingencies.

Little is a post Strunk case of a donation from a mentally disabled / ill incompetent being authorised.<sup>220</sup> Little did not, however, follow the 3 justifying requirements laid down in Richardson. In Little the contingencies of donation were minimal but authorisation occurred without the procedure being evidently urgent and clinically there were reasonable alternatives, although donation by the incompetent was the best option. Little placed importance on the consent of the incompetent's parents, a close relationship between donor and recipient and the involvement of the court.<sup>221</sup> The law is now in some confusion. Not only is there uncertainty about what are the justifying requirements for donation but also uncertainty about how strict these requirements are. The factors given importance in Little are very basic and quite irreconcilable with the stricter Richardson requirements.

#### **7.3.3.3. The Involvement of the Adult Incompetent in the Decision.**

What is the relevance of the incompetent adult's views in determining what is in his/her best interests? Re Y is silent on the question of the involvement of the adult incompetent. The view of a mentally ill minor has been described as "a very material factor" by Balcombe LJ in Re W<sup>222</sup> - although this case actually shows how an incapacitated view can be easily ignored; an ideal opportunity to treat the incompetent person's decision about treatment when incompetent as an anticipatory decision was rejected.<sup>223</sup>

With specific regard to living donation it has been commented that "it is unthinkable that the 'best interests' test could be satisfied if the donor objected to the donation."<sup>224</sup> However, the Law Commission has taken a modified approach in its recommendation that those providing care, "...should not enforce the doing of anything to which the person

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<sup>220</sup>Little 576 SW 2d at 499.

<sup>221</sup>Ibid at 498-499.

<sup>222</sup>[1992] 3 W.L.R. 758, 776.

<sup>223</sup>On the significance of the patient's previous known views see also the U.S. case of Re Conroy [1985] 486 A.2d 1209 which held that the significance of such views will vary according to their remoteness, consistency, thoughtfulness and specificity.

<sup>224</sup>Ibid.



objects...This provision is not to preclude the taking of steps which are necessary to avert a substantial risk of serious harm to the person concerned.”<sup>225</sup> Within this approach, if an incompetent objected to donation it could still go ahead - although the only possible situation in which it could be enforced would be where the prospective recipient has a close and essential relationship with the incompetent, there are no other donor and without donation by the incompetent there would be substantial risk of serious harm to the incompetent. Examples could be: where the prospective recipient would die without the donation leaving the incompetent traumatised; *or* the recipient has an essential therapeutic relationship with the incompetent which due to illness (s)he could not maintain without a transplant.

Beyond the general need for absence of objection there will not be many situations in which it is acceptable to go ahead without the explicit agreement of the adult incompetent; it is difficult to show that the donation will have psychological benefit without such an agreement. One of the consequences of this is that it may be difficult to accept donation by people who are severely (mentally) disabled<sup>226</sup> unless the procedure is in their best interests because it averts significant harm - examples of this situation being provided in the previous paragraph.

#### **7.3.4. Jurisdictions Prohibiting Living Organ Donation by Incompetent Adults.**

Some jurisdictions exclude legally incompetent adults from being donors of any body material including Turkey,<sup>227</sup> Cyprus,<sup>228</sup> Slovakia,<sup>229</sup> Russian Federation,<sup>230</sup> Syrian Arab Republic,<sup>231</sup> Tunisia,<sup>232</sup> Cuba,<sup>233</sup> Ecuador,<sup>234</sup> Panama,<sup>235</sup> Bolivia,<sup>236</sup> Romania,<sup>237</sup> and

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<sup>225</sup>Draft Bill clause 5 (Law Comm No. 231 at p62).

<sup>226</sup>[1996] Med L Rev 205-207 at 207.

<sup>227</sup>Law of 1979 at section 7 requires a physician is to reject an organ for donation where the donor is "unable to take their own decision for mental or psychological reasons."

<sup>228</sup>Section 7 of Law No. 97 of 1987 On the Removal and Transplantation of Biological Materials of Human Origin.

<sup>229</sup>Section 46(1) of Law of 24 August 1994 - see *IDHL*, 1995, 46(2), 151-154.

<sup>230</sup>Law of 22 December 1992 at section 3.

<sup>231</sup>Law No. 31 of 23 August 1972 On the Removal and Transplantation of Organs From the Human Body at section 2(3).

<sup>232</sup>The donor must be in possession of all mental capacities under Law No. 91-22 of 25 March 1991 On The Removal and Transplantation of Human Organs at section 2.

<sup>233</sup>Law No. 41 of 13 July 1983 On Public Health at section 80.

<sup>234</sup>Law No. 64 of 26 May 1987 Reforming The Health Code at section 1.



Poland.<sup>238</sup> A few laws have requirements probably equating with capacity: Spanish law<sup>239</sup> requires donors to be, "in full possession of their mental capacities;" Slovenian<sup>240</sup> and Algerian<sup>241</sup> laws require the donor to have necessary / proper judgement, respectively. Greek law requires that the donor must not have been declared incompetent by a court or be in the care of a guardian appointed by a court.<sup>242</sup> By implication, prospective donors not declared incompetent by a court might still be declared incompetent to donate based on a de facto inability to give true consent.<sup>243</sup>

Some laws implicitly prohibit donation of organs by incompetent adults simply by requiring the donor to consent.<sup>244</sup> The laws of Hong Kong and UK have no general

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<sup>235</sup>Law No. 10 of 11 July 1983 Regulating the Transplantation of Organs and Anatomical Parts, and Laying Down Other Provisions at section 10(1).

<sup>236</sup>Section 4 Regulations of the Use of Organs and Tissues 15 March 1982.

<sup>237</sup>1996 Law Regarding The Harvesting and The Transplantation of Human Tissues and Organs at Article 4(1).

<sup>238</sup>Law of October 26, 1995 Regulating the Removal and Transplantation of Human Cells Tissues and Organs.

<sup>239</sup>Law No. 30 of 27 October 1979 section 4(b).

<sup>240</sup>Article 10 of Law of 1996 Of The Transplantation of Human Body Parts For the Sake of Medical Treatment.

<sup>241</sup>Section 183 of law of 1985.

<sup>242</sup>Law No. 1383 of 2 August 1983 On the Removal and Transplantation of Human Tissues and Organs section 5(a).

<sup>243</sup>Hence the stringency or otherwise of Greek law would only be determined by case law.

<sup>244</sup>Belgian law requires consent to be given freely and knowingly (Law of 13 June 1986 On The Removal and Transplantation of Organs section 8(1)). Danish law requires that the patient understand the nature of the intervention, its consequences, and the risks (Law No. 402 of 13 June 1990). Norwegian law requires that the physician ensure that the donor has understood the nature of the operation and its possible consequences (Law No. 6 of 9 February 1973 at section 1). Conversely Bulgarian law although stating the need for consent implies that legal representatives may consent on behalf of the donor (Ordinance of 1976 at section 2 states "it shall be necessary to obtain the written consent of the patient and also where the patient is a minor or subject to limited deprivation of rights, that of the parents or legal representatives. In the case of minors and persons subject to total deprivation of rights the consent of the parents or guardians shall be obtained). The Belarus Draft law emphasises the need for the donor to give consent in full awareness of the facts and also interestingly adds that the recipient must not be dependent on the recipient (Article 8 of Draft law of 1995 On the Donation and Transplantation of Human Organs and Tissues). South Australia requires that the donor, "in the light of medical advice furnished to him understands the nature and effect of the removal and the nature of transplantation" (The Transplantation and Anatomy Act 1983 at section 10(1)(b)). Iraqi law appears only to express the need for the donation to be voluntary which leaves the position regarding incompetents as unclear see Resolution No. 776 of 9 June 1981 of The Revolutionary Command Council Promulgating Law No. 60 of 1981 On Kidney Transplant Operations. The same position is reached in Indian law - section 2 of The Transplantation of Human Organs Act (No. 42 of 1994) - see *IDHL*, 1995, 46(1), 34-38 at p34. See also Lebanon (Decree No.109 of 16 September 1983 On the Removal of Human Tissues and Organs for Therapeutic and Scientific Purposes. Section 1 states that the physician to ascertain that the donor has properly understood the risks of the intervention), Venezuela (Law of 19 November 1992 On The Transplantation of Organs and Anatomical Materials in Human Beings at section 12 - see *IDHL*, 1995, 46(3), 329-330), Peru (Supreme Decree No. 014-88-SA of 19 May 1988 at section 15 lays down that the consent must be free, conscious



provisions relating to competency but in each case have an authority set up under the law. This authority will only authorise non-genetically related organ donations where it is satisfied that certain conditions are met. One of these conditions is that the donor has given informed consent - which effectively precludes all persons who are incompetent to donate<sup>245</sup> although such persons could *potentially* become a *genetically related donor* under principles of common law.<sup>246</sup>

A number of jurisdictions have the approach of the WHO Guiding Principles which recommend the exclusion of organ donation by persons incompetent to donate by reason of mental illness or disability<sup>247</sup> while allowing donation of regenerative material.<sup>248</sup> Even donation of regenerative material by incompetent adults may be subjected to special restrictions. For instance, the law of Netherlands allows for donation of regenerative material by incompetent adults on behalf of first or second degree relatives who are in danger of losing their life and such danger is not readily avertible in any other way and the donor attaches considerable importance to averting the danger threatening the life of the blood relative concerned. Consent by parents (or guardian / legal representative) and by the judge of the children's court is required and the donor, if possible, as well as the person consenting on behalf of the donor are to be informed of the nature and object of the removal and its foreseeable consequences for the donor.<sup>249</sup> Despite applying to donation of non-regenerable tissue, The Netherlands provision will not allow incompetent donation of liver segment because under this law material cannot be

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and express (similar provision in repealed Law No. 23415 of 1 June 1982 at section 7(b)), Vietnam (Law of June 1989 On Protection of Public Health section 30(1)) and Uruguay (Decree No. 660/991 of 4 December 1991 at section 1 - see *IDHL*, 1994, 45(1) at 38).

<sup>245</sup>Except were there to be an instance of ULTRA being wrongly satisfied of capacity.

<sup>246</sup>For these provisions in respective laws see HOTA 1989 section 2(3) and Hong Kong Ordinance No. 16 of 1995 (The Human Organ Transplant Ordinance) at section 5(4) - see *IDHL*, 1995, 46(3), 325-327 at 327.

<sup>247</sup>WHO Guiding Principle 3 states that where an organ is being removed from the body of an adult living donor that donor should be "sufficiently informed to be able to understand and weigh the risks, benefits and consequences of consent" (Human Organ Transplantation: A Report On Developments Under the Auspices of WHO (1987-1991) WHO, 1992, 8).

<sup>248</sup>The definition of organ for these purposes includes tissue. This is effectively suggesting that incapacitate adults should not become donors. However this must be subject to Guiding Principle 4 under which a minor rendered incapacitate by a mental disability or illness can in principle become a donor of regenerative material (Human Organ Transplantation: A Report On Developments Under the Auspices of WHO (1987-1991) WHO, 1992, 10).

<sup>249</sup>Law of 24 May 1996 at section 4(1) - 4(3). (also Hans Akveld, communication with EUROTOLD and response to legal questionnaire).



removed from an incompetent adult if it's removal will have lasting effects upon the donor's health.<sup>250</sup>

Several further jurisdictions have legislation which is framed in such a way that they result in *some competent persons* being unable to be organ donors. In France, a 1994 law prohibits donation by adults who are the subject of legal protection measures.<sup>251</sup> This is supplemented by a general requirement for consent which would indirectly restrict donation to persons with sufficient competence.<sup>252</sup> In Mexico there is prohibition on persons in a state of diminished awareness in *addition* to incompetent persons. Some laws *might* result in some competent persons not being allowed to be organ donors: Zimbabwe prohibits donation by persons mentally disordered or defective;<sup>253</sup> Sri Lanka,<sup>254</sup> Northern Territory,<sup>255</sup> Western Australia,<sup>256</sup> Tasmania<sup>257</sup> and Queensland<sup>258</sup> persons not of sound mind; Paraguay persons with a disability prescribed by law.<sup>259</sup> These laws can be viewed as an unacceptable restriction on the autonomy of adults who may be *de facto* competent to donate even with their mental 'difficulty' or 'condition.'

### 7.3.5. Court Involvement.

Portuguese law is unique amongst transplant legislation in explicitly requiring court authorisation of living donation by an incompetent adult.<sup>260</sup> This approach is commendable, particularly in the context of organ donation.

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<sup>250</sup>Ibid at section 4(1).

<sup>251</sup>Law No. 94-654 of 29 July 1994 at Article L.671-4.

<sup>252</sup>Article L. 665-11 *ibid*.

<sup>253</sup>The Anatomical Donations and Post Mortem Examinations Act No. 34 1976 at section 13(3) these terms are given the meaning under the Mental Health Act 1976.

<sup>254</sup>The Transplantation of Human Tissues Act, No. 48 of 1987 at section 7(2)(b)(ii).

<sup>255</sup>Law No. 121 of 1979 An Act To Make Provision For and In Relation To The Removal and Use of human Tissues, For Post Mortem Examinations, For the Definition of Death and for Related Purposes at section 8(1)(b).

<sup>256</sup>Act No. 116 of 1982 The Human Tissue and Transplant Act 1982 at section 8(1)(b).

<sup>257</sup>The Human Tissue Act 1985 at section 9(c)(ii).

<sup>258</sup>The Transplantation and Anatomy Act 1979-1984 at section 10(b).

<sup>259</sup>Law No. 836180 of 15 December 1980 Promulgating the Health Code at section 279.

<sup>260</sup>It provides that, "the removal of organs or tissues from majors who are incompetent by reason of a psychological anomaly shall only be possible with the authorisation of a court" (Law No. 12 of 22 April 1993 On the Removal and transplantation of Human Organs and Tissues at section 8(5)). Psychological anomaly is not defined but presumably has an ambit which reaches beyond persons who are incapacitate to donate by reason of mental illness or disability. Court authorisation is limited to regenerative material (section 6(3) *ibid*); effectively meaning that living organ donation, except perhaps liver donation, would not be accepted. Argentinean law of 1993 only applies to material which is not naturally regenerable (Law No. 24193 of 24 March 1993 On The Transplantation of Organs and Anatomical Materials at section 1).



The Law Commission recommended organ and bone marrow donation by incompetent adults be treated as within a 'special category' of procedures under English law which should require the involvement of a Court forum.<sup>261</sup> The Commission noted that this would require amendment of existing regulations under HOTA which require donors not classed as genetically related to have capacity.<sup>262</sup> Although it would be very rare to have justifying reasons for non-genetically related adult incompetent donation, it is possible. For instance, an incompetent could have a relationship with a prospective recipient spouse, partner or even friend that is so essential as to warrant (in the presence of additional justifying factors) donation as much as in a genetically related case. The Commission must be commended for the justice of its approach.

Under current general principles of English law, the House of Lords in Re F considered court involvement was desirable but not obligatory for proposed sterilisation (Lord Griffiths being the exception viewed Court involvement as mandatory) and Lord Bridge drew an analogy with organ donation. The Court of Appeal had drawn a similar analogy with Neill LJ suggesting that for these types of controversial procedure prior Court approval should be standard practice. It may well be that for the purposes of liability doctors can proceed without fear of legal liability, provided that the procedure can be shown to be in the best interest of the incompetent individual and someone with the legal authority to consent on the incompetent person's behalf has done so. Indeed this approach is consistent with the case of Re Y which stated that court involvement was "appropriate" without saying it was mandatory.<sup>263</sup>

In the US the necessity of Court involvement would depend on the evolution of the law in each particular state. In the cases brought to court so far, court involvement has been a pre-requisite simply because the relevant law has provided that only the Court has authority to allow donation.<sup>264</sup>

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Donation of such tissue appears to be restricted to capacitate persons although this is not certain from the IDHL text (see e.g. section 13 which requires consent to have been freely given. However the law has not been presented in full - see *IDHL*, 1994, 45(1), 35-36).

<sup>261</sup>The preliminary conclusion to this effect (*HMSO*, 1993, Paper No. 129, at 6.1 - 6.9) was confirmed as a final recommendation )Law Com No. 231 at p85).

<sup>262</sup>The Human Organ Transplants (Unrelated Persons) Regulations 1989 (SI 1989 No. 2480) - reg 3(2)(b).

<sup>263</sup>[1996] Med L Rev 204-205 at 205.

<sup>264</sup>Strunk v Strunk (1969 445 SW 2d 145 (ky CA)); Little v Little (Tex Civ 1979) 576 SW 2d 493; Pescinski, 67 Wis 2d 4, 226 NW 2d 180; In Re Richardson (La App 1973), 284 So 2d 185; In Re Guardianship of Eberhardy (1981), 102 Wis 2d 539, 307 NW 2d 881. In the state of Washington the state attorney can authorise this procedure.



### 7.3.6. Conclusion.

Current law in this area is something of a patchwork - many transplant laws have missed the opportunity to comprehensively address this area leaving the legal position to be determined by reference to the position of minors under transplant law as guidance<sup>265</sup> along with general principles of law which typically lack certainty in their application to LDT. Jurisdictions may be advised to use legislation to remedy these problems at the earliest convenience.

Regarding the different approaches to this area which currently exist, it may be concluded that the vulnerability of adult incompetents makes it a reasonable approach to prohibit organ donation by this group. It is also reasonable to adopt the approach that someone else may authorise the donation on behalf of the adult (e.g. a judge or legal guardian) *providing* strict conditions are met. However, it may be extremely difficult for organ donation by an incompetent adult to be justified in practice - at least in countries where cadaveric transplant and dialysis are sufficiently well established and available that there would generally be no medical emergency or lack of reasonable alternatives on which to establish the case for donation; this was actually very much the position when Little was decided - it's justifying criteria appear to allow donation too easily. Even 11 years before Little, in Strunk, dissenting opinions were stressing the viability of cadaveric kidney transplantation. Where viable alternatives exist the use of mentally disabled / ill donors seems unwarrantedly invasive and utilitarian. Other criticisms can be levelled at the approach of law in this area. Strunk itself can be criticised for giving limited focus to exploring the wishes of the incapacitate<sup>266</sup> - a connected argument being

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<sup>265</sup>Judges faced with such a lack of specific provision might draw on the relatively parallel situation of donation of body materials by incompetent minors. This would help to deduce the relevant principles in a number of jurisdictions (e.g. Denmark, Belgium, Federal Republic of Germany, Norway, Finland, Costa Rica and South Africa) where there is mention of minors but no mention of non-age related mental capacity. Some jurisdictions allow minors to donate in such a situation subject to the consent of others and in some cases donor agreement. The point can be made that whereas minors may come to take a view that their actions were of benefit a non-age related incapacitate may never do so (partly depending on the nature of the incapacity). This would make the justification of benefit to the donor harder to substantiate in this situation than with minors.

<sup>266</sup>The Strunk expert psychiatric testimony can be criticised as too heavily evaluative rather than facilitative - a more person centred approach could have reaped benefits (see chapter 4 and Appendix 4).



that psychiatric testimony is too heavily relied upon with its independence and validity being questionable.<sup>267</sup>

The justificatory conditions for donation by this group are similar to those applying to incompetent minors. Adult donations where competency is in question could also be brought before the same legal forum recommended for minors. This forum could apply strict justifying criteria including the valuing of incompetent autonomy through a *minimum* that the incompetent agreed with the donation - in a meaningful way or at least in a way that evidence clearly suggested (s)he would have decided if competent. A further prior condition for donation would be that it had prospective psychological value significantly outweighing prospective (largely physical) detriment and that the detriment was maintained below a certain level; this would help to assure that the incapacitate was not being exploited for transplant's overall utility for society.

#### **7.4. Overall Conclusions on Capacity in Organ LDT.**

Two major points arise in the context of capacity in organ LDT. The first concerns the need for strong and comprehensive provisions that protect a vulnerable group from abuse by specifying clear conditions within which donation is acceptable. These conditions should be set within the context of all proposed donations by minors and adults with questionable capacity being brought before a legal or quasi legal forum which would probably be set up under transplant legislation. Transplant legislation, although currently patchy, provides certainty and seems like the vehicle through which the ethical and legal issues arising in this area can be comprehensively dealt with. The problem with general principles of law is that although they are somewhat flexible they were never designed in anticipation of dealing with an area involving such complex and unique ethical and legal issues. General principles also lack the degree of certainty and high profile required to make practitioners more aware of the issues and encouraged to put forward minors and adult incompetents for living organ donation in appropriate situations.

The rarity of organ donations by minors and adults of questionable capacity is such that the judicial forum described above would not be overburdened even if its remit was to accept cases from a number of jurisdictions (e.g. the whole EU or the whole of the US).

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<sup>267</sup>See e.g. T.S.Szasz, *Law, Liberty and Psychiatry: An Inquiry Into The Social Uses of Mental Health Practices*, MacMillan, 1963



Over time, however, such a forum would build up expertise in the area and its existence would help to allay the concerns of medical practitioners who, by being able to pass on such ethically and legally troublesome cases to an expert body, might actually be encouraged to consider the possibility of living organ donation more often in this area - particularly in the context of older minors. Nevertheless, living organ donation amongst minors and adult incompetents is likely to remain rare, particularly in Europe; it must be stated that in the context of incompetent donors this is comforting - even kidney donation is a detrimental and serious procedure for an incompetent to take on, particularly in an age where dialysis is common and the focus should be moving towards supplying sufficient organs without resort to radical options.

The other major point arising from this area of medical ethics and law is the whole axis of autonomy. Michael Gunn makes the general point that, "respect for autonomy is the guiding principle in health law."<sup>268</sup> This principle is no less critical when adults with a mental condition and minors are at issue, it is simply harder to apply. Gunn has suggested that the importance of autonomy leads to it being,

"essential that a test for capacity sets a standard which allows as many people as possible to make their own treatment decisions."<sup>269</sup>

Some jurisdictions fail to not meet Gunn's goal in the context of living organ donation by outright exclusion or undue restriction of minors and person's with a mental condition who are de facto capacitate. Current law and medical practice also reflect a culture of authority of the physician and medical enterprise which as well as limiting patient autonomy reinforces dependency and incapacity to make decisions. On the other hand, the unique position of the donor has ensured the wishes of minors and incompetent adults are given some respect. The level of respect is more clearly evidenced with minors than with incompetent adults. The latter group may still be burdened by a pervasive societal assumption that if you are an incompetent decisions can be made on your behalf without significant reference to your involvement, values and wishes. In this context the Law Commission was right to infuse its recommendations with an underlying principle of maximising the opportunities for decision-making involvement of incompetent persons.

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<sup>268</sup>Gunn, The Meaning of Capacity, *Med Law Review*, 1994 (Spring), 2, 8-29 at 8.

<sup>269</sup>Gunn, *ibid*.



The person-centred model of negotiation might be adapted for use in this context<sup>270</sup> as a legislatively embodied requirement to focus on therapeutic facilitation to help uncover deeper levels of understanding and viewpoint of the incapacitate,<sup>271</sup> thereby more significantly grounding decisions in autonomy.

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<sup>270</sup>The success of person centred therapists in working with, "unmotivated, deeply disturbed and often highly uncommunicative persons" such as schizophrenics, and disturbed children is relevant here (see E.T.Gendlin, Client-Centred Developments in Psychotherapy With Schizophrenics, *Journal of Counselling Psychology*, 1962, 9, 205-211 and Sub-verbal Communication and Therapist Expressivity: Trends in Client-Centred Psychotherapy with Schizophrenics, *The Wisconsin Psychiatric Institute Bulletin*, 1 (1961); Rogers, Some Learnings From a Study of Psychotherapy With Schizophrenics, *Pennsylvania Psychiatric Quarterly*, 1962, 3-15; V.Axline, Play Therapy. *Houghton Mifflin*, 1947.

<sup>271</sup>See Appendix 4 for discussion of the work of Carl Rogers and the person-centred approach.



## **Chapter 8 Financial Exchange in Organ LDT.**

Over decades ideas about what financial exchange is acceptable in organ transplantation (and body materials generally) have been put forward. In an area raising strong emotions and perspectives there has been more thesis and antithesis than synthesis. The logical first step to transcending the myriad of conflicting approaches is to demarcate different aspects and levels of potential exchange in organ transplantation. This provides a framework for analysing current legal regulation of organ LDT and a sound basis to examine the merits of different approaches to exchange and regulation of exchange. Assessing the merits of different approaches involves assessing the rights of relevant parties (professionals, donors, recipients, entrepreneurs and the public at large) in the light of empirical data about the most efficient system of procurement for organ transplantation as a whole (in terms of numbers, quality, cost etc.).

### **8.1. Demarcating Levels and Aspects of Exchange in Organ Transplantation**

There are 4 main dimensions of potential exchange to analyse: exchange in the organisation of transplantation; exchange in the practice of transplantation; exchange in transplant participation; *and* exchange in funding transplantation.

#### **8.1.1 Financial Exchange in the Organisation of Transplantation**

Within all jurisdictions those who organise transplantation gain financial reward for doing so. The level of payment has ethical implications: 'too little' may be unfair treatment; 'too much' is equally unfair. Some notion of fair payment is critical, but what this notion could comprise is debatable. To some, charging what the market can bear is fair, to others fairness would represent an amount akin to what might be expected for similar work, to others still it involves a more egalitarian notions such as payment more comparable with a average wage with perhaps some premium for the skills, training and experience of the organisers.



Another issue in terms of payment of organisers is the matter of who pays the bill - this will be examined in 8.1.4. Finally there is the issue of ethics of payment related to who is doing the organising. Should there be limits on who can earn financial reward from the process? Should reward be limited to designated medical establishments or should it be expanded to include other persons or organisations who might advertise, broker and organise the financial exchange? This is a question of the economic rights of those persons and organisations viewed within the context of the rights of others discussed below.

### **8.1.2. Financial Exchange in the Practice of Transplantation.**

What is fair payment of practitioners where should it payment come from?

### **8.1.3. Financial Exchange in Transplant Participation.**

The key issues here are ones of payment to the donor and/or the donors nominees. There are a multiplicity of variations in terms of levels of payment. Current terminology used for certain types of payment can be confusing. For instance 'rewarded gifting' can be anything from a payment that is nominal to one that goes beyond any concept of reasonable payment for the donor's losses. A suggested demarcation of the key degrees of payments is as follows:

1. Reasonable payment of the donor for financial losses resultant from the process of donation. This would usually be accompanied by free medical care in relation to the health consequences of donation. Payment of reasonable financial loss could include such things as loss of earnings due to hospitalisation / recovery from donation, costs of home help/childcare, travel and subsistence expenses *etc.*
2. Reasonable payment for unexpected health consequences resulting from donation. This would basically be a kind of no-fault compensation scheme whereby the donor would get paid if, for instance, there was sepsis at the wound site or failure of the remaining kidney.



3. Reasonable payment for expected health consequences resulting from donation.  
This is essentially paying the donor for what is physically endured - such as scarring at the wound site, pain and suffering *etc.*
4. Payment of a reasonable wage to the donor for time and effort in the process of donation (any payment already made for lost earnings would be deducted from the calculation).
5. Payment above a reasonable wage to the donor - either subject to limits or based on what the market will bear.

The above payments could operate in combination or alone. The first two levels of payment can meet no real ethical or practical objection of significance since while a donor voluntarily subjects him / herself to risk (s)he is engaged in something viewed as for the benefit of others and should not be left to bear the economic consequences of any of those risks materialising. Payment they do not even compromise the volunteering nature of donation. They merely act to ensure that the donor does not suffer a 'double whammy' of losing out financially as well as enduring donation. The third to fifth levels of payment are where more controversy lies.

The third level of payment for intrinsic health consequences can just viewed as reasonable expenses, much the same as those often given to research subjects for example. The arrangement is quid-pro-quo rather than profit making; the donor simply gets something back for pain and harm endured. Nevertheless, this level of payment meets objections for violating the volunteering concept of donation. The fourth level goes into the realm of 'fair trade' - an economic exchange of reasonable payment for effort, time and suffering endured in the act of donation. The fifth level involves a more capitalistic scheme of profit making. This system places the market as primary with other principles such as equity as secondary - particularly if prices are based on what the market would bear, slightly less so if capped (perhaps by a government quango called Offbod<sup>1</sup>) where necessary in the interest of consumers and / or competition. principles. Who was paying for the organs would also have a bearing on equity.

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<sup>1</sup>Office of Fair Body Trading. Trading rules might include discounts for off-peak organs.



Some methods of payment fail to fit neatly into one level. For instance, payment of a fixed fee by the state, recipient or insurance companies could be anything from the third to the fifth level of payment in practice depending on whether it was nominal, estimated according to likely donor health consequences / risks and financial losses or at a profit making level. places the market as primary with other principles such as equity secondary.

#### **8.1.4. Financial Exchange in Funding Transplantation.**

Costs of transplantation have to be paid somehow and the method of funding has ethical implications. The arrangements in most countries are collectivist; money is pooled from the public. The pool or pools are then used to pay for all costs. Private insurance companies act as pools and/or the state does in terms of a national health insurance plan. In some cases the arrangements remain individualist; some countries have little take-up of private insurance and no nationalised health care plan, or more specifically no funding for transplantation. Which approach is more appropriate for transplantation?

The problem with individualist approaches and to a lesser extent private insurance is that some people will not be able to afford to pay for healthcare; distribution of transplantation would to some extent be based on wealth. On the other hand a state nationalised system, while making wealth irrelevant in distribution, involves an element of 'collectivist coercion' with the public having resources compulsorily 'syphoned off' them (i.e. tax) to meet objectives that are largely set at a central level. Within this system healthcare also becomes a 'right' which may be detrimental to any notion of individual responsibility for one's health. This debate raises too many issues to be answered within this PhD. One thing that could be stated is that the public, who in one way or another pay for transplantation have a right to value for money in terms of a system that is operated efficiently, maximising impact and minimising costs.



To some people a free profit-making market in transplantation would be the most efficient approach and one that respects the right to 'make a profit.' Most, however, would consider that the system will be more efficient and fair if payment is limited to a 'reasonable amount based on services rendered' for those involved at various points of the process. This would involve excluding 'excessive wages' and 'excessive profits' by those operating the insurance system, the organisers of the transplants, practitioners and donors. The amount could be paid at either a market rate or a fixed rate. Within a regulated system with restrictions (for instance with a fixed rate for organs, paid for by the state and retaining the present waiting list system etc.) or a rampant system where anything can be donated to anyone at any price with availability of organs for potential recipients depending largely on one's ability to pay the market price or even bid on an auction basis.

## **8.2. Legal Regulation of Commercial Dealings in Organs.**

### **8.2.1. Introduction**

For decades, international organisations have condemned trade in human organs.<sup>2</sup> The Council of The Transplantation Society,<sup>3</sup> Council of Europe and WHO<sup>4</sup>

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<sup>2</sup>The first attempt to Internationally respond to commercial dealings in organs was back in 1970 when the Committee of Morals and Ethics of the Transplantation Society adopted a statement including the rubric that, "(t)he sale of organs by living donors is indefensible under any circumstances." *Ann of Intern Med*, 1971, 75(4): 631-633.

<sup>3</sup>Guidelines of 1985 on transplantation which stressed that surgeons / physicians should not advertise, the transplant team should establish the altruistic, non-profit, motivations of the donor, unrelated donors should have an independent advocate to ensure informed consent is given without pressure and there should be no payment except for reimbursement of lost work earnings and expenses (see *Lancet*, 1985, 2, 715-6). For further details of International responses see Human Organ Transplantation: A Report On Developments Under The Auspices of WHO (1987-1991), *WHO*, 1991 at 16.

<sup>4</sup>The WHO prohibitions has a lengthy genesis. The 37th World Medical Assembly which endorsed the World Medical Association Inc.'s 'Statement on Live Organ Trade' calling on the governments of all countries to take effective steps to prevent commercial use of human organs. This view of organ trading was confirmed by the 39th World Medical Assembly and World Health Assembly Resolution 40.13 (Declaration on Human Organ Transplantation, Madrid, Spain, October 1987. See Appendix of WHO's book, Legislative Responses to Organ Transplantation, *Martinus Nijhoff*, 1994). This resolution suggest that trade is, "inconsistent with the most basic human values and contravenes the Universal Declaration of Human Rights and the spirit of the WHO constitution." The United Nations Universal Declaration of Human Rights is probably contravened (depending on one's opinion!) as suggested given that Article 1 of the declaration provides that human beings, "should act towards one another in the spirit of brotherhood," Article 3 provides for security of person which could easily be violated by the excesses of commercial dealings while article 25(1) providing the, "right to a standard of living adequate for the health and well-being" of the individual and his / her family may be violated



frameworks have promoted prohibition. WHO Guiding Principles provide a comprehensive framework of prohibition of trade as follows:

"The human body and its parts cannot be the subject of commercial transactions.

- Accordingly, giving or receiving payment (including any other compensation or reward) for organs should be prohibited."<sup>5</sup>
- "Advertising the need for the availability of organs, with a view to offering or seeking payment, should be prohibited."<sup>6</sup>
- "It should be prohibited for any person or facility involved in organ transplantation procedures to receive any payment that exceeds a justifiable fee for the services rendered."<sup>7</sup>
- "In the light of the principles of distributive justice and equity, donated organs should be made available to patients on the basis of medical need and not on the basis on financial or other considerations."<sup>8</sup>

The Council of Europe's Resolution (78)29<sup>9</sup> states that no substance may be offered for profit. Further Council of Europe statements are similar.<sup>10</sup> An important

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in the sense that giving up an organ has physical dangers and no-one should have to be drawn to it by fact of desperate poverty (signed 10 dec, 1948, G.A.Res 217 A(III) U.N.Doc.A/810 at p71). Later Resolution WHA42.5 noted the lack of success in preventing trafficking in human organs and called upon member states, "to take appropriate measures to prevent the purchase and sale of human organs for transplantation" adding that it was, "anxious to prevent the exploitation of human distress, particularly in children and other vulnerable groups, and to further the recognition of the ethical principles which condemn the buying and selling of organs for purposes of transplantation" (May 1989, WHA42/1989/RE C/1,7 see WHO's book, *Legislative Responses to Organ Transplantation*, Martinus Nijhoff, 1994). Guiding Principles for Organ Transplantation were prepared and endorsed by the 44th World Health Assembly on 13 May 1991 in Resolution WHA44.25 to set out the parameters the assembly felt organ transplantation should take place within. For these Guiding Principles see Human Organ Transplantation, ED 87/12, 19 Nov 1990 pages 4-5. See also Appendix of WHO's book, *Legislative Responses to Organ Transplantation*, Martinus Nijhoff, 1994

<sup>5</sup>Guiding Principle 5.

<sup>6</sup>Guiding Principle 6.

<sup>7</sup>Guiding Principle 8.

<sup>8</sup>Guiding Principle 9.

<sup>9</sup>On Harmonization of Legislations of Member States to Removal, Grafting and Transplantation of Human Substances adopted by The Committee of Ministers of the Council of Europe on 11 May 1978 Article 14

<sup>10</sup>The 3rd Conference of European Health Ministers Paris 16-17 November 1987 confirming the anti-commerce stance of the above resolution. There is some recognition that the sale of organs is a problem affecting Europe as well as other parts of the world. The Health Ministers Conference voiced this and its final text concluded that, "a human organ must not be offered for profit by any organ exchange organization, organ banking centre or by any other organization or individuals whatsoever."



distinction made by international organisations is between making money from the buying and selling of organs on the one hand and simply compensating donor losses on the other. To this end the Council of Europe's Resolution states that;

"loss of earnings and any expenses caused by the removal or preceding examination may be refunded. The donor, or potential donor, must be compensated independently of any medical responsibility, for any damage sustained as a result of a removal procedure or preceding examination, under a social security or other insurance scheme."

WHO Guiding Principles are similar on this point.<sup>11</sup>

In 1969 a survey was published in the International Digest of Health Legislation focusing partly on the anti-commerce aspects of legislation<sup>12</sup> and indicating that only Italy had a law prohibiting commercial transactions. Since then most transplanting jurisdictions have legislatively prohibited commerce (provisions on compensation for loss will be discussed in section 8.2.5.).<sup>13</sup> Exceptions include Bulgaria,<sup>14</sup> El

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Final Text app.II at 13 reprinted in *IDHL*, 39, 277. The report at this conference went as far as to say that, "to ensure that the donation of an organ is not tainted in any way," and that, "it is totally spontaneous and completely without payment," a ban should be made, "on the removal of non-regenerative organs from a living human who is not closely and genetically related to the recipient." Council of Europe, *Organ Transplantation: Ethical and Social-Cultural Problems Raised by Organ Transplantation* (Paris Conference of European Health Ministers, Nov 16-17, 1987) at 15-16. This and other International responses to commercialization in organ transplantation are discussed in WHO's book *Legislative Responses to Organ Transplantation*, *Martinus Nijhoff*, 1994.

<sup>11</sup>Principle 5 prohibiting trade states that: "...This Principle does not prohibit payment of reasonable expenses incurred in donation, recovery, preservation and supply of organs for transplantation."

<sup>12</sup>Use of Human Tissues and Organs for Therapeutic Purposes: A Survey of Existing Legislation, *IDHL*, 1969, 20, 3. For another account of law relating to this area see D.J.Wolfslast, 'Legal Aspects of Organ Transplantation: An Overview of European Law.' University Gottingen, Gottingen, Germany (A copy is kept by the EUROTOLD Project). On legislation generally see: 'Commerce in Human Organs: Some International Responses' (*WHO* 1991); 'List of Jurisdictions Known to WHO HQ to Have Legislation on Organ Transplantation (above ref); S.S.Fluss, 'Preventing Commercial Transactions in Human Organs: An International Overview of Regulatory and Administrative Measures' (*WHO*, *IDHL*, 1989 (May), 154-163); P.Lee et. al., 'Worldwide Legal Regulations for Obtaining Corneas,' *Cornea*, 1990, 11(2) at p102-107: and most importantly the World Health Organization's recent comprehensive book, 'Legislative responses to Organ Transplantation,' *Martinus Nijhoff*, 1994. See also *EUROTOLD's* Legisearch database (Ed D.Price and Austen Garwood-Gowers).

<sup>13</sup>As stated in chapter 4 some jurisdictions have no transplant law while other's have legislative provision only for cadaveric donation. In these instances there is no legal prohibition of the buying and selling of organs although medical practitioners engaging in such activities may be subjected to sanctions from their respective national medical organisations. This is the case with Ireland and with Germany where the Transplantation Code, binding on all physicians conducting transplantation states



Salvador,<sup>15</sup> Japan,<sup>16</sup> Libyan Arab Jamahiriya,<sup>17</sup> Malaysia,<sup>18</sup> Norway,<sup>19</sup> Pakistan,<sup>20</sup> Philippines,<sup>21</sup> Sweden,<sup>22</sup> Tonga<sup>23</sup> and Vietnam.<sup>24</sup> The problem with not having prohibition is that professional guidelines do not affect participant and broker / middleman commercial dealings. Some jurisdictions are developing legislation that will prohibit commerce including Albania,<sup>25</sup> Estonia<sup>26</sup> and Israel.<sup>27</sup>

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that "any trade in organs or any commercialisation of the transplantation... sector is, in principle, excluded" See Human Organ Transplantation, WHO, 1991 at p21. Section 3 of the GDR Ordinance of 4 July 1975 is still in force in the new German Landers that were formerly East Germany. This section prohibits commercial dealings. Legislation for Germany has been proposed for a number of years (see A.Tuffs, Germany: A Step Nearer a Transplant Law? *Lancet*, 1993, 341 at 363-4. In Malta there is no law but guidance issued by the Medical Council to the Health Authorities stress the need for clear evidence of genuine (presumably non-commercial) motivation particularly where a donation by a complete stranger is at issue. Liechtenstein does not have the technical capacity to undertake transplantation and hence has not considered it necessary to either regulate or consider the issue. However S.S.Fluss of the World Health Organization has stated in a more recent paper that Liechtenstein does have legislative prohibition (Organ and Tissue Transplantation in The European Union (Ed Y.Englert), *Martinus Nijhoff*, 1995 at 76). Egypt appears to allow only living related donation which are performed free of charge at State expense, this is not yet declared in formal law however (Fluss, Organ and Tissue Transplantation In The European Union (ed Y.Englert), *Martinus Nijhoff*, 1995, 79). In Saudi Arabia there is no law but it is considered prohibited to buy or sell human organs in line with the "Unified Arab Draft Law on Human Organ Transplants" (see Human Organ Transplantation, WHO, 1991, 25). Laws are currently under consideration for Estonia, Albania, a unified Germany and Belarus (new law) all of these countries are likely to prohibit commercialisation assuming the law is passed. Commerce is a concern for Germany with reports of Germans being involved in the buying of kidneys as recipients and being involved in marketing organs. Reports exist of West German's openly offering to buy kidneys for transplant purposes from donors in Europe and the Third World. See *Los Angeles Times*, 1988, November 13, Pt.1, 22, Cols 1-3. The names of two prominent West German brokers and the cost of their 'transplant packages' are laid out in The Organ Grinders, South: *The Third World Magazine*, 1989, Apr, 77-78. One of them actually announced plans to sell in Great Britain (see *The Independent* (London), 1989, Jan 30, 2 col 4. The President of the West German Medical Association has condemned the trade in kidneys saying it treats third world people as 'living organ banks' to be cut up for sale.

<sup>14</sup>Ordinance No. 15 of the Minister of Public Health On the Transplantation of Human Organs, 30 April 1976. However, WHO was informed in 1993 that a Draft law for Bulgaria was under discussion, section 5 of which would prohibit commercial dealings in organs.

<sup>15</sup>Decree No. 955 Promulgating the Health Code 11 May 1988.

<sup>16</sup>Law No. 70 of 8 December 1989.

<sup>17</sup>Law No. 4 of 10 March 1982.

<sup>18</sup>The Human Tissues Act, 8 March 1974.

<sup>19</sup>Law No. 6 of 9 February 1973 On Transplantation, Hospital Autopsies, Donations of Bodies etc.

<sup>20</sup>Ordinance No. III of 24 July 1990 To Provide for the Establishment of the Sindh Institute of Urology and Transplantation.

<sup>21</sup>Presidential Decree No. 856 of December 1975 Promulgating the Code on Sanitation. However this position is likely to change, a bill addressing sale of organs was introduced. EUROTOLD is unaware whether this has become law yet (see p26 of Human Organ Transplants, WHO 1991).

<sup>22</sup>Law No. 831 of 8 June 1995 (*IDHL*, 1996, 47(1), 28-30) has no provision on this point and nor did it's repealed predecessor Law No. 190 of 15 May 1975.

<sup>23</sup>The Corneal and Tissue Grafting Act 1958.

<sup>24</sup>Law of June 1989 On Protection of Public Health.

<sup>25</sup>The process of developing legislation was begun in earnest in 1996.

<sup>26</sup>Legislation during 1998 seems likely.

<sup>27</sup>The status and breadth of Israel's position is uncertain - The WHO has heard that in the Public Health Ordinance new provisions will prohibit commerce in organs (S.S. Fluss p81 in Organ and Tissue Transplantation In The European Union (ed Y.Englert), *Martinus Nijhoff*, 1995).



Most laws define the ambit of body materials that is to be covered by the prohibition on commercial dealings. Sometimes the prohibitions relate only to organs and not to tissues, for instance UK law (see particularly section 7(2) HOTA 1989) and Hong Kong law. Occasionally prohibitions are limited by reference to types of organ subject to prohibition e.g. Dominican Republic Law corneas only,<sup>28</sup> an initial Italian law only kidneys.<sup>29</sup> Austria<sup>30</sup> and Singapore<sup>31</sup> only covers cadaveric donation.<sup>32</sup>

### **8.2.2. Prohibition of Profit From Organ Donation.**

The general intention of 'anti-commerce provisions' is to prevent profit being made out of organ donation it is not to prevent compensation for expense incurred by a donor hospital in a removal procedure or other necessary activities associated with transplantation.<sup>33</sup> Most jurisdictions prohibit commercial dealings in organs generally, irrespective of the parties or organs involved. Transplant laws in Finland,<sup>34</sup> France,<sup>35</sup> Indonesia,<sup>36</sup> Luxembourg<sup>37</sup> and Spain<sup>38</sup> do not prohibit the medical profession from profiting from the donation of an organ (e.g. by charge a recipient for organ donation and the organ itself) although this might be prohibited under general principles of law on public policy grounds.

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<sup>28</sup>Law No. 60-88 of 30 August 1988 On the Donation of Corneas at sections 11-12.

<sup>29</sup>Law No. 458 of 26 June 1967. See *IDHL*, 1969, 20, 3. A later Italian law apparently relates to all organs (section 19 and 20 of Law No. 644 of 2 December 1975) however EUROTOLD has found reliable information on Italy difficult to obtain.

<sup>30</sup>Section 62a of the Hospitals Law of 18 December 1956, as amended by the Federal Law of 1 June 1982.

<sup>31</sup>The Human Organ Transplants Act 1987.

<sup>32</sup>Other laws with limited scope of prohibition include Zimbabwe's law which states that only an authorised institution can receive payment otherwise it will be an offence to deal for fee profit or remuneration. This leaves a legal door open to organs being sold by institutions such as hospitals. Act No. 34 of 1976 at section 17. Blood and blood products are excepted from this provision.

<sup>33</sup>Undefined terms describing the ambit of activities being restricted, for instance organ dealings must not be for 'profit,' remuneration or 'commercial' need to read in this light.

<sup>34</sup>States that there shall be no remuneration paid to the donor or his Estate. Law No. 780 of 25 August 1994 at section 11 (see *IDHL*, 1995, 46(1), 33). See Lillich, Transplanting Organs From Living Donors: An International Regime or more Free Enterprise, in *Finnish Yearbook of International Law*, 1990 (copy held at WHO).

<sup>35</sup>Prohibits payment being given to the donor. Law No. 94-654 of 29 July 1994 at Article L. 665-13 *IDHL*, 1994, 45(4), 474-482 at 474.

<sup>36</sup>Govt. Regulation No. 18 of 16 June 1981 On Clinical and Anatomical Autopsies and Transplantation of Human Organs and Tissues at section 16.

<sup>37</sup>Establishes a principle of non-remuneration of the donor. Law of 25 November 1982 Regulating the Removal of Substances of Human Origin at section 16.

<sup>38</sup>Crown Decree No. 426 of 22 February 1980 for the Implementation of Law No. 30 of 27 October 1979 On the Removal and Transplantation of Organs at sections 5 and 12.



United Kingdom law has the most comprehensive method of prohibition of profit from organ donation within Europe in the HOTA 1989. Section 1 of HOTA prohibits any dealings or adverts of commercial nature. This theme is elaborated on in some detail to cover any possible angle of involvement in the organ market. It prohibits supplying, offering to supply, soliciting supply, negotiating / initiating of arrangement for payment / supply / offer of supply, various aspects of advertising with a commercial purpose and managing/controlling a body of persons (e.g. a company) involved in such activities.<sup>39</sup> Indian law<sup>40</sup> draws extensively on the

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<sup>39</sup>The section states that;

1(1)A Person is guilty of an offence if in Great Britain he-

- (a) makes or receives any payment for the supply of , or for the offer to supply, an organ which has been or is intended to be removed from a dead or living person and is intended to be transplanted into another person whether in Great Britain or elsewhere;
- (b) seeks to find a person willing to supply for payment such an organ as is mentioned in paragraph (a) above or offers to supply such an organ for payment;
- (c) initiates or negotiates any arrangement involving the making of any payment for the supply of , or for an offer to supply, such an organ; or
- (d) takes part in the management or control of a body of persons corporate or unincorporate whose activities consist of or include the initiation or negotiation of such arrangements.

(2) without prejudice to paragraph (b) of subsection (1) above, a person is guilty of an offence if he causes to be published or distributed, or knowingly publishes or distributes, in Great Britain an advertisement-

- (a) inviting persons to supply for payment any such organs as are mentioned in paragraph (a) of that subsection or offering to supply any such organs for payment; or
- (b) indicating that the advertiser is willing to initiate or negotiate any such arrangement as is mentioned in paragraph (c) of that subsection.

(3) In this section "payment" means payment in money or money's worth but does not include any payment for defraying or reimbursing

- (a) the cost of removing, transporting or preserving the organ to be supplied; or
- (b) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his supplying an organ from his body.

(4) In this section "advertisement" includes any form of advertising whether to the public generally , to any section of the public or individually to selected persons.

(5) A person guilty of an offence under subsection (1) above is liable on summary conviction to imprisonment for a term not exceeding three months or a fine not exceeding level 5 on the standard scale or both; and a person guilty of an offence under subsection (2) above is liable on summary conviction to a fine not exceeding level 5 on that scale. General Medical Council Guidance for Doctors on Transplantation of Organs from Live Donors advises that, "The Council Regards it as unethical and improper for a doctor to take part in any way in the trading of organs or the transplantation of organs obtained from donors whose consent has been given as a result of any form of undue influence. A doctor who behaves in this way is liable to disciplinary proceedings by the Council." *General Medical Council Supplement News Review*, December 1992 point 2. The Council's Guidance should be read in the light of section 1(3)a of HOTA (allowing reimbursement of medical costs in removing, transporting and preserving in supplying an organ and donor expenses and loss of earnings reasonably and directly attributable to supplying an organ) meaning it is perfectly acceptable for doctors to take part in such reimbursement. The Council's guidance was based on their belief that: "(i) human organs should not be the subject of commercial transactions: any donation of organs must be made altruistically, as a gift; (ii) where human organs are bought or sold, transplantation will be governed by money rather than by the medical interests of the donors and recipients, with the vulnerable and the poor inevitably exposed to exploitation." (point 3 *ibid*). The duties of doctors include satisfying themselves that the donation has occurred without financial or other



approach in UK law and Hong Kong's law does even more so.<sup>41</sup> HOTA and pursuant regulations also contain specific requirements relating to preventing / sanctioning commerce in non-genetically related donations. Hong Kong's law also takes this approach.<sup>42</sup> Polish law states that, "it is prohibited to demand or accept any payment or any profits for the harvesting of cells, tissues and organs" and adds that "any person who for the purpose of material gain purchases or sells other people's cells, tissues or organs or act as an agent in the purchase and sale or takes part in transplanting illegally obtained cells, tissues or organs" is liable to criminal sanctions.<sup>43</sup> Peruvian law prohibits payment, any other compensation, benefits, financial or monetary advantages, or reciprocal arrangements of a similar or analogous nature.<sup>44</sup> Chile's law<sup>45</sup> prohibits payment but also has an unusual, and useful, requirement that living donors must make a sworn declaration that they have received no compensation, valuable consideration, or other material benefit from the recipient or from other third parties.<sup>46</sup> Iraq's law states that sale or purchase of organs in any form is prohibited and imposes a duty on physicians that if they are aware that organs are subject of sale or purchase are to refrain from proceeding with a transplant.<sup>47</sup> Further provisions are listed below in Figure 4.

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material benefit or undue influence of any kind (point 7) while in no circumstances may doctors participate in or encourage in any way the trade in human organs from live donors. They must not advertise for donors nor make financial or medical arrangements for people who wish to sell or buy organs (point 6). A doctor independent of the transplantation team must assess the motivation of the donor (point 7). Each member of the team must retain and exercise individual ethical responsibility towards the patient - *ibid* at point 8.

<sup>40</sup>One of the most important provisions bearing in mind its scale of commercially motivated transplantation.

<sup>41</sup>In prohibiting making buying, selling, negotiating, managing, advertising organs on a commercial basis. Ordinance No. 16 of 1995 at section 2 (*IDHL*, 1995, 46(3), 325-327 at 325).

<sup>42</sup>In prohibiting making buying, selling, negotiating, managing, advertising organs on a commercial basis. Ordinance No. 16 of 1995 at section 2 (*IDHL*, 1995, 46(3), 325-327 at 325).

<sup>43</sup>Articles 18 and 20 respectively of Law of 26 October 1995 (Copy held at EUROTOLD). Article 20 also lays down the criminal sanctions. All jurisdictions prohibiting trade have criminal sanction attached to breach of their provisions.

<sup>44</sup>Supreme Decree No. 014-88-SA of 19 May 1988 at section 3.

<sup>45</sup>Section 145 and 152 of the Health Code as amended by Law No. 18.173 of 26 November 1982 law prohibits payment or any contract or agreement promising or supplying organs and tissues.

<sup>46</sup>Section 3(f) of Regulations issued on 3 June 1983.

<sup>47</sup>Decree No. 698 of 27 August 1986 of the Revolutionary Command Council Promulgating Law No. 85 of 1986 On the Transplantation of Human Organs at section 3.



**Figure 4: Further Provisions Prohibiting Profit Making From Organ Donation.**

Argentina,<sup>48</sup> Australian state laws of Queensland, South Australia,<sup>49</sup> Northern Territory,<sup>50</sup> Capital Territory,<sup>51</sup> New South Wales,<sup>52</sup> Tasmania<sup>53</sup> Western Australia,<sup>54</sup> and Victoria,<sup>55</sup> Belarus (Draft Law),<sup>56</sup> Belgium,<sup>57</sup> Bolivia,<sup>58</sup> Brazil,<sup>59</sup> Canada's model law,<sup>60</sup> Colombia,<sup>61</sup> Costa Rica,<sup>62</sup> Cuba,<sup>63</sup> Cyprus,<sup>64</sup> Denmark,<sup>65</sup> Guatemala,<sup>66</sup> Honduras<sup>67</sup> Hungary,<sup>68</sup> India,<sup>69</sup> Kuwait's law,<sup>70</sup> Lebanon,<sup>71</sup>

<sup>48</sup>Prohibits "any financial gain or other benefit in exchange for the donation of organs..or any intervention for financial gain." Section 27 of Law No. 24193 of 24 March 1993 (*IDHL*, 1994, 45(1), 35-36 at 35.

<sup>49</sup>The Transplantation and Anatomy Act 1983 contains a prohibition of trading in tissue under Part VII.

<sup>50</sup>Act No.121 of 1979 (The Human Tissue Transplant Act 1979) at section 24(1). Under s24(3) the minister of health can authorize such an arrangement however. The penalty for breaking this law is a \$500 fine or imprisonment for 3 months which is quite typical of anti commercialisation provisions.

<sup>51</sup>Ordinance No.44 of 1978 on Transplantation and Anatomy prohibits trading in tissue in part VII.

<sup>52</sup>Act No.164 of 1983 - The Human Tissue Act prohibits trading of tissue in part VI.

<sup>53</sup>The Human Tissue Act 1985 prohibits commercial dealings in organs (part IV).

<sup>54</sup>The Human Tissue and Transplant Act 1982 (No.116) sections 29 (trading) and 30 ( advertising).

<sup>55</sup>The Human Tissue Act 1982 (No.9860) prohibits trading in tissue (part VIII).

<sup>56</sup>Prohibits the buying and selling of human organs is under section 4 of Draft Law of 1995.

<sup>57</sup>States that organs and tissues, "may not be provided for profit, irrespective of the parties involved. Law No. .32 of 13 June 1986 On the Removal and Transplantation of Organs at section 4(1).

<sup>58</sup>Section 90 of the Health Code promulgated in 1978, prohibits trade but allows "interchange" for charitable purposes. The former law of former Yugoslavia prohibited commercial dealings in organs (Section 4 of Law of 15 July 1982 On the Conditions Governing the Exchange and Transport of Parts of the Human Body for Transplantation for Therapeutic Purposes).

<sup>59</sup>Constitution of Federative Republic 5 Oct 1988 at section 199 states that organs must not be the subject of any commercial transactions.

<sup>60</sup>The Uniform Human Tissue Donation Act 1990 section 15 states that, "no person shall buy, sell or otherwise deal in (except where lawful before the act and act complied with) organs."

<sup>61</sup>Decree No.1172 of 6 June 1989 section 17 prohibits donation for other than, "therapeutic, teaching, or research purposes.

<sup>62</sup>Prohibits any remuneration or compensation for organs and anatomical materials and makes procuring organs with a view to financial gain is an offence. Law No. 5560 of 20 August 1974 on Human Transplants at section 13 and 14 respectively.

<sup>63</sup>Law No. 41 of 13 July 1983 and Decree No. 139 of 4 February 1988 requires donation to be free and for humanitarian reasons.

<sup>64</sup>Prohibits commercial agreements or transactions. Law No. 97 of 1987 On the Removal and Transplantation of Biological Materials of Human Origin at section 60.

<sup>65</sup>States that it is an offence to offer or receive any form of compensation in respect of the removal or transceiver or to collaborate with these activities. Law No. 402 of 13 June 1990 at section 20(3).

<sup>66</sup>Section 10 of the Regulations in Dealing in Organs and Tissues From Human Beings and Cadavers (Govt. Order No. 74086 of 26 September 1986) states that the provision of organs and tissues must be free of charge.

<sup>67</sup>Section 5 of the Law On the Transplantation and Removal of Human Organs and Tissues (Decree No. 131 of 23 Nov 1982) states that no payment shall be made in respect of human organs and tissues.

<sup>68</sup>States that donation of an organ may be made only in the absence of payment and no person may request or get remuneration. Ordinance No.18 of 4 November 1972 of the Minister of Health for the Implementation of the Provisions of Law No. II of 1972 On Health Relating to the Removal and Transplantation of Organs and Tissues at section 2.

<sup>69</sup>The Transplantation of Human Organs Act (No. 42) 1994 at section 2k (*IDHL*, 1995, 46(1), 34-38).

<sup>70</sup>Decree-Law No. 55 of 20 December 1987 On Organ Transplantation at section 7 states that organs may not be sold or bought in any fashion nor any material benefit be obtained in relation to them.



<u>Malawi,</u> <sup>72</sup> <u>Mexico</u> <sup>73</sup> <u>Panama,</u> <sup>74</sup> <u>Romania,</u> <sup>75</sup> <u>Russian Federation,</u> <sup>76</sup> <u>Singapore,</u> <sup>77</sup> <u>Slovakia,</u> <sup>78</sup> <u>Slovenia,</u> <sup>79</sup> <u>South Africa,</u> <sup>80</sup> <u>Sri Lanka,</u> <sup>81</sup> <u>Syrian Arab Republic,</u> <sup>82</sup> <u>Ticino (Swiss canton),</u> <sup>83</sup> <u>The</u> <u>Netherlands,</u> <sup>84</sup> <u>Tunisia,</u> <sup>85</sup> <u>Turkey,</u> <sup>86</sup> <u>USA model law</u> <sup>87</sup> and <u>Venezuela,</u> <sup>88</sup>
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### 8.2.3 Ancillary Prohibitions Relating to Advertising.

In addition to preventing profit making from organ donation, a small number of jurisdictions explicitly prohibit the solicitation of business for organs. This is a fairly

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<sup>71</sup>Decree (No.109) of 16 September 1983 On the Removal of Human Tissues and Organs for Therapeutic Purposes at section 4 states that, "no form of compensation shall be provided in relation to the donation of tissues and organs."

<sup>72</sup>States that selling, buying and supplying of organs is prohibited as is unauthorised export. No.14 of 1990 at section 16 and export is also illegal - see section 20.

<sup>73</sup>Federal Regulations of 16 August 1976 On the Use of Human Organs, Tissues and Cadavers at section 26 prohibits remuneration for organs.

<sup>74</sup>No. 10 of 11 July 1983 at section 4 prohibits remuneration for organs.

<sup>75</sup>States that the harvesting and transplantation of organs may not be subject to any transaction. Law of 1996 at Article 2(1). Subject to the fact that the hospital undertaking the transplantation meets any medical expenses (Article 13(1)).

<sup>76</sup>Prohibits buying and selling of organs. Law of 22 December 1992 of the Russian Federation on the Transplantation of Human Organs and/or Tissues at section 1.

<sup>77</sup>Medical (Therapy Education and Research) Act 1972 at section 15.

<sup>78</sup>Appears to prohibit payment for an organ. Section 46(5) of Law of 24 August 1994. (*IDHL*, 1995, 46(2), 151-157 at 155).

<sup>79</sup>Prohibits the giving or receiving of payment or any other financial benefits for human body parts. Law of 1996 at Article 4 (copy held at EUROTOLD).

<sup>80</sup>Section 28 of the Human Tissue Act No. 65 of 1983 lays down stringent prohibitions on payment relating to import, acquisition or supply of tissue or gamete.

<sup>81</sup>Law No. 48 of 1987 The Transplantation of Human Tissues Act at section 17 prohibits buying, selling or otherwise disposing of organs.

<sup>82</sup>No. 31 of 23 August 1972 at section 6 prohibits remuneration for organs.

<sup>83</sup>Laws prohibit commercial dealings in organs. Law of 18 April 1989 On Health Promotion and Co-ordination of the Health Sector at section 15. Several Swiss Cantons have endorsed the guidelines of the Swiss Academy of Medical Sciences which lay down that organ transplantation must be provided free of charge but do not comprehensively prohibit commercial dealings (see Human Organ Transplantation, *WHO* 1991).

<sup>84</sup>Law of 24 May 1996 at section 2 specifies that consent to removal of an organ is deemed to be null and void if such consent has been given in order to receive a compensatory amount greater than that of expenses, including lost earnings, deriving directly from the removal of the organ (*IDHL*, 1996, 47(4), 469-475 at 470). Organ donation can only occur within organ centres which are only given authorisation if they are operating for non-profit-making purposes (section 25)

<sup>85</sup>Law No. 91-22 of March 1991 On the Removal and Transplantation of Human Organs prohibits commerce in transplantation.

<sup>86</sup>Prohibits, "the removal or purchase or sale of any organ or tissue for profit or any other kind of remuneration shall be prohibited." Law No. 2238 of 1979 On the Removal, Storage, Transfer and Grafting of Organs and Tissues at sections 3 and 4 respectively.

<sup>87</sup>Many states have adopted the prohibition on commercial dealings in organs within the National Organ Transplant Act 1984 at section 10, see Human Organ Transplantation, *WHO* 1991.

<sup>88</sup>Law of 19 November 1992 at section 7 prohibits payment or compensation for organs, tissues, derivatives, or anatomical materials removed for therapeutic purposes (*IDHL*, 1995, 46(3), 329-330).



common feature in new transplant legislation such as Belarus Draft law,<sup>89</sup> Poland,<sup>90</sup> Russian Federation,<sup>91</sup> UK,<sup>92</sup> Hong Kong,<sup>93</sup> India.<sup>94</sup> Romanian<sup>95</sup> and French laws<sup>96</sup> prohibit advertising intended to promote donation of elements and products of the human body for the benefit of a specific person or for the benefit of a specific establishment or agency. This effectively bans all commercial advertisements. Other laws with prohibitions in this field include Turkey,<sup>97</sup> Queensland,<sup>98</sup> Western Australia,<sup>99</sup> Singapore,<sup>100</sup> Northern Territory<sup>101</sup> Capital Territory<sup>102</sup> and New South Wales.<sup>103</sup>

Some jurisdictions allowing commercial adverts thereby leave a loophole in commerce prohibition; it being possible to get around the spirit of prohibition by advertising in the jurisdiction concerned to conduct commercialised transplant in a jurisdiction without prohibition.

#### **8.2.4. Additional Regulation Relating to Donor-Recipient Relationship.**

In line with the Council of Europe's Resolution (78)29<sup>104</sup> and WHO Guiding Principles<sup>105</sup> some statutory regimes restrict or exclude organ LDT between persons

<sup>89</sup>Section 4 of Draft Law of 1995, copy held at EUROTOLD.

<sup>90</sup>Article 20 of Law of 26 October 1995.

<sup>91</sup>Law of 22 December 1992 of the Russian Federation on the Transplantation of Human Organs and / or Tissues at section 1.

<sup>92</sup>Section 1 of HOTA 1989.

<sup>93</sup>Ordinance No. 16 of 1995 at section 2 (*IDHL*, 1995, 46(3), 325-327 at 325).

<sup>94</sup>The Transplantation of Human Organs Act (No. 42) 1994 at section 2k (*IDHL*, 1995, 46(1), 34-38 at 34).

<sup>95</sup>Law of 1996 at Article 4(2).

<sup>96</sup>Article 665-12 of Law No. 94-654 of 29 July 1994.

<sup>97</sup>Law No. 2238 of 1979 On the Removal, Storage, Transfer and Grafting of Organs and Tissues at sections 3 and 4 respectively.

<sup>98</sup>Section 41 *ibid*.

<sup>99</sup>The Human Tissue and Transplant Act 1982 (No.116) at section 29 for trading and section 30 for advertising..

<sup>100</sup>Medical (Therapy Education and Research) Act 1972 at section 15.

<sup>101</sup>Act No.121 of 1979 (The Human Tissue Transplant Act 1979) at section 24(1). Under s24(3) the minister of health can authorise such an arrangement however. The penalty for breaking this law is a \$500 fine or imprisonment for 3 months which is quite typical of anti commercialization provisions.

<sup>102</sup>Ordinance No.44 of 1978 on Transplantation and Anatomy prohibits trading in tissue in part VII.

<sup>103</sup>Act No.164 of 1983 - The Human Tissue Act prohibits trading of tissue in part VI.

<sup>104</sup>Article 4 which suggests that the removal of non-regenerative organs from living persons not closely and genetically related to the potential recipient should in exceptional cases where there are good chances of success. Council of Europe, Organ Transplantation: Ethical and Social-Cultural Problems



without an existing emotional and / or genetic relationship.<sup>106</sup> There provisions are partly aimed at reducing or eliminating the possibility of commercial dealings in organs, some of them make specific reference to this fact.

Indian<sup>107</sup> and UK law require all donations to be screened (by an Authority set up under the law) for commercial motivation except those between close genetic relatives. Hong Kong has a similar provision but scrutiny of spousal relationships over 3 years standing is not required. UK law (mirrored by Hong Kong law<sup>108</sup>) attempts to prevent / sanction commercially motivated non-genetically related donation. Under section 2(3) of HOTA to grant authority for such a donation ULTRA must, amongst other things, be satisfied that no payment has been made in contravention of section 1 of the Act.<sup>109</sup> This requirement, repeated in regulation 3(1)a of The Human Organ Transplants (Unrelated Persons) Regulations 1989, is designed to provide 'extra cover' against commercial motivation by requiring medical practitioners to put forward proposed non-genetically related donations for authorisation by ULTRA. Continuing this theme regulation 3(2)c requires ULTRA to be satisfied that the donors consent was not caused by an offer of an inducement.<sup>110</sup> The main motivation for greater scrutiny and regulation of non-genetically related donation<sup>111</sup> is that non-genetically related donation is considered more susceptible to

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Raised by Organ Transplantation (Paris Conference of European Health Ministers, Nov 16-17, 1987) at 15-16.

<sup>105</sup>Guiding Principle 3 suggests that living donation should generally be limited to genetically related persons exceptions being made in the case of bone marrow and other acceptable regenerative tissues..

<sup>106</sup>E.g. laws of France, Slovenia, Sweden, Portugal, Russian Federation, India, Hong Kong, UK. Additional restrictions exist in several countries in the specific situation of minor donation. Further analysis of this area is provided in chapter 7.

<sup>107</sup>Section 8 of Act No. 42 of 1994, *IDHL*, 1995, 46(1), 36.

<sup>108</sup>Ordinance No. 16 of 1995, *IDHL*, 1995, 46(3), 326.

<sup>109</sup>In other words not in contravention of all the various prohibitions laid down in the section.

<sup>110</sup>Regulation 3(1)c limits the scope of 3(2)c to those cases in which the organ is *not* being removed primarily for medical treatment of that donor - hence for instance regulation 3(2)c would not apply to situations in which a living person's heart was used for donation as an incidental factor in a medically required removal of that heart from the donor. In other words there appears to be a distinction between persons whose primary role is that of a patient and those whose role is completely that of being a donor, with greater protective regulation for the latter.

<sup>111</sup>ULTRA has produced 3 Annual Reports and usually examine more than 10 cases each year. This would seem to indicate that the Act has at least not significantly deterred transplant professionals from accepting unrelated donors which was a fear at the time the Act was passed. In fact the contrary may have happened in that transplant professional may feel more secure about putting forward non-closely genetically related donors because there is another body doing the ethical scrutiny for them and potentially as such protecting them from any scandal of commercial dealings (providing they themselves are not part of any dealings). A similar view to this was put forward by the Chair of ULTRA in a 1996 meeting with David Price.



commercial motivation. 'Gifts' etc. between genetic relatives could contravene the Act but the main 'evil' that the Act is directed towards is more fully commercial transactions. These are obviously most likely to occur between strangers or people who have 'manufactured' an emotional or legal relationship for the purpose, as the Under Secretary for Health stated, during the passing of the Act, Parliament "(could not) rule out the possibility of non-genetic relationships being formed solely for the purpose of the operation or of pressure - economic or otherwise - being brought to bear upon a donor to submit to a transplant operation."<sup>112</sup>

Nethertheless, the bureaucratic rigour of going through ULTRA might seem somewhat insulting to persons who have been close for a long period, e.g. some couples who have been married or cohabiting many years. Hong Kong's law is perhaps better for allowing donations by spouses of over 3 years standing to go unscrutinised by its parallel authority.<sup>113</sup>

Kishore has suggested that restrictions and exclusions of non-genetically related donors are unrealistic and interfere with the continued development of altruism in society.<sup>114</sup> However, strangers are more likely to come forward in the spirit of

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<sup>112</sup>The then Parliamentary Under Secretary of State For Health in the House of Commons (HC Deb, 6 July 1989). The Presidents of The International Transplantation Society and British Transplantation Society alleged in 1985, "that British surgeons are transplanting kidneys into Indian and Pakistani patients who have paid living donors to give up a kidney" (The Times (London), May 13, 1985 at 32 column 1). Bearing this in mind there was a real possibility of fake marriages being instituted for donation. The Act is often superficially pointed out to have been passed with haste but in fact nothing was done following the above statement. Lillich states that the pleas of the Presidents for the British Government to legislate to make such practices illegal had fallen on deaf ears until later reports of Turkish peasants being flown in to London and paid to be kidney donors (Transplanting Organs from Living Donors: An International Regime or More Free Enterprise, *Finnish Yearbook of International Law*, 1990. This case involved the exclusive private London hospital Wellington Humana where two Turkish people had been paid £2,000 each to donate their kidneys (see *The Independent* (London), Jan 18, 1989, at 2 columns 1-3). Dr Raymond Crockett was struck off by the General Medical Council for his involvement in this affair. The media outrage appeared to finally get the Secretary of Health to do something about a practice he had said in 1985 was "outrageous" and would be reviewed by Parliament "urgently." (see D.Brahams, 'The Outcry Over the Humana Affair,' *Lancet*, 1985, 1, 285). During the debates the government was criticised by the opposition for dragging its feet on the issue. One Conservative M.P. spoke in favour of the commercial market (see Parliamentary Debates (House of Commons) Second Reading Committee (16.5.89) and Standing Committee A (8.6.89)). This may indicate one of the underlying reasons that the government did not act faster; a dislike of 'controlling or interfering with market forces' - preventing person's doing as they please with their body being a part of this.

<sup>113</sup>Ordinance No. 16 of 1995 at section 5(1).

<sup>114</sup>"There is no scope for dogmatic postures. Open-mindedness should be the approach while dealing with an issue like organ transplantation. Families are not unconnected or antagonistic fragments of



entrepreneurship than the spirit of universality. The only way to allow strangers to express altruism with limited risk of commerce would be for their donated organs to go into a 'pool' with anonymity between donor and recipient. This system is widely utilised for blood donation. It might be practical despite the limited 'shelf life' of organs. However risks and definite consequences are much higher in donating organs than donating blood; there might be considerable ethical objection to a stranger assuming such risks and consequences. The counter to this is that, as rescuers, people regularly assume high levels of risk and consequence for strangers. What, for instance, the difference between rescuing someone from a burning house and donating. If non-commerciality and non-psychopathology are assured stranger-donation becomes a highly liberated form of giving; untroubled by intra-familial pressures and conflicts that not infrequently impinge on familial donations and expressing a noble human solidarity.

At this stage stranger donation is unlikely to achieve sufficient public and professional consensus to become a common reality. However, laws should at least to be subtle enough to accept emotionally related donors like spouses and close friends<sup>115</sup> who can be a significant source of organs.

### **8.2.5 The Donors Assurance Against Negative Economic Consequences From Donation.**

Negative economic consequences from donation are potentially wide-ranging. They can include lost earnings/holiday entitlements, travel and subsistence expenses, childcare and reconnaissance expenses, reduction of job security/dismissal, reduction of ability to get life insurance and, within a private health care system, costs of

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society. After thousands of years of continuous efforts the individuals on this search have attained a state of organic and functional integration. Atomisation of society on the basis of consanguineous proximities amounts to reversal of this holistic trend." Organ Donation: Consanguinity Vs Universality - An Analysis of Indian Law, Forthcoming Publication, *Trans Proc*, Dec 1996, copy held at the EUROTOLD Project.

<sup>115</sup>A good example here is the acceptance by ULTRA in 1996 of a lung lobe from a friend of the prospective recipient; the primary justification being that 2 lobes were required and only one was available within the family.



healthcare/affectation of the status of health care insurance. Does law and practice adequately assure against such negative consequences?

#### **8.2.5.1. Assurance Within Transplant Law.**

Transplant law lacks uniformity in its approach to assuring donors against negative economic consequences. While a small number of transplant laws (including the Belarus draft law,<sup>116</sup> Belgium,<sup>117</sup> Finland,<sup>118</sup> France,<sup>119</sup> Panama,<sup>120</sup> Slovenia<sup>121</sup> and Spain<sup>122</sup>) assure donors as a matter of right, some jurisdictions (including Hong Kong<sup>123</sup> India,<sup>124</sup> Luxembourg,<sup>125</sup> The Netherlands,<sup>126</sup> Singapore for cadaveric,<sup>127</sup> Ticino,<sup>128</sup> Tunisia<sup>129</sup> UK,<sup>130</sup> USA<sup>131</sup> and the Australian state laws of Northern

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<sup>116</sup>Article 11 of draft law of 1995 (copy held at EUROTOLD).

<sup>117</sup>States that, "the crown shall make rules concerning the compensation of living donors at public expense or by the social security agency designated by it. Such compensation shall cover both the costs and loss of income directly resulting from the provision of an organ." Law No. 32 of 13 June 1986 at section 4(2).

<sup>118</sup>This has a limited arrangement in place whereby donors having to take a day or more off work receive a daily allowance. Law No. 780 of 25 August 1994 at section 11 (*IDHL*, 1995, 46(1), 33). The daily allowance is in accordance with the provisions of Health Insurance Law (364/63).

<sup>119</sup>Allows reimbursement of expenses incurred in the process of donation. Arrangements are being made to reimburse living donors of their necessary costs. Article 665-13 of Law No. 94-654 of 29 July 1994 (*IDHL*, 1994, 45(4), 473-482 at 474).

<sup>120</sup>States that, "should the donor request he shall be entitled to payment of hospital medical expenses, laboratory charges, and similar expenses incurred by him, as well as compensation for loss of earnings during his absence from work by reason of examinations and other necessary procedures." Law No. 10 of 11 July 1983 at section 4. The recipient is also entitled to free medical care - section 4.

<sup>121</sup>Law of 1996 at Article 4.

<sup>122</sup>States that, "the living donor shall be guaranteed the care necessary for his recovery as well as the coverage of any costs incurred as a result of the donation and operation." Crown Decree No. 426 of 22 February 1980 at section 5.

<sup>123</sup>Ordinance No. 16 of 1995 at section 2 (*IDHL*, 1995, 46(3) at 325).

<sup>124</sup>The Transplantation of Human Organs Act (No. 42) 1994 at section 2 (*IDHL*, 1995, 46(1), 34-38 at 34) see Organ Donation: Consanguinity -Vs - Universality. An Analysis of Indian Law by Dr R.R. Kishore, manuscript held at EUROTOLD Project, soon to be published in Transplantation Proceedings.

<sup>125</sup>Law of 25 November 1982 at section 16 allowing for reimbursement of loss of revenue and other expenses that may be occasioned by organ removals.

<sup>126</sup>Law of 24 May 1996 - section 7 states that the donor may be compensated for the expenses referred to in section 2 which are compensation for expenses including lost earnings deriving directly from the removal of the organ.

<sup>127</sup>Medical Therapy and Research Act 1972 at section 14(3).

<sup>128</sup>Law of 18 April 1989 at section 15.

<sup>129</sup>Law No. 91-22 of 25 March 1991

<sup>130</sup>Under section 1(3) b of HOTA including, "any expenses or loss of earnings incurred by a person so far as is reasonably and directly attributable to his supplying an organ from his body." See also Circular No. 308 of 7 September 1989 On the Arrangements for The payment of Costs and reimbursement of expenses Incurred by the Removal from Living Donors of Human Organs or Bone Marrow Intended for Transplantation.



Territory,<sup>132</sup> South Australia,<sup>133</sup> Tasmania<sup>134</sup> and Western Australia<sup>135</sup>) only explicitly allow it - leaving it to the discretion of government department or practitioners as to what form and even whether assurance occurs in practice. The majority of jurisdictions do not address assurance for donors within transplant law; the extent of assurance in practice depending much on the vagaries of whether and to what extent a donor is covered incidentally via labour and welfare law and deliberately by voluntary financial support (e.g. from a hospital, employer or recipient). Some of the areas least likely to be compensated for are childcare, home reconnaissance (e.g. home help) and travel costs - these being dependent on welfare law (which is typically becoming more limited) and voluntary financial support (which is sporadic<sup>136</sup>).

Some limits to assurance are designed to avoid it being a 'back door' route to paying donors for their services. For instance, Indian,<sup>137</sup> Hong Kong<sup>138</sup> and UK<sup>139</sup> laws allow expenses or loss of earnings incurred by the donor in supplying the organ from his body *provided they are reasonable and directly attributable to the donation*. Other limits derive primarily from a lack of legislative attention to this issue than any deliberate policy. For instance, in creating HOTA, UK legislators were so 'myopically concerned' with preventing 'trade and other malpractice' that they failed to explicitly debate whether or not donor assurance should be a matter of right. Meanwhile, Finnish law manages to provide for compensation of the donors lost

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<sup>131</sup>National Organ Transplants Act has been adopted by many states in respect of its explicit allowance that the donor's expenses may be provided for. Section 10 of the Act see also p19 of Human Organ Transplantation, WHO 1991.

<sup>132</sup>The Human Tissue Transplant Act No. 121 of 1979 at section 24(5).

<sup>133</sup>The Transplantation and Anatomy Act 1983 section 35(4).

<sup>134</sup>The Human Tissue Act 1985 at section 27(3).

<sup>135</sup>The Human Tissue and Transplant Act No. 116 of 1982 at section 29(3).

<sup>136</sup>European hospitals only provide support sporadically - see chapters 10. One possible point of hesitancy for hospitals is that they might feel wary of making such payments for fear of being misconstrued as a commercial incentive, or uncertainty as to the legal position.

<sup>137</sup>The Transplantation of Human Organs Act (No. 42) 1994 at section 2 (*IDHL*, 1995, 46(1), 34-38 at 34) see Organ Donation: Consanguinity -Vs - Universality. An Analysis of Indian Law by Dr R.R. Kishore, manuscript held at EUROTOLD Project, soon to be published in Transplantation Proceedings.

<sup>138</sup>Ordinance No. 16 of 1995 at section 2 (*IDHL*, 1995, 46(3) at 325).

<sup>139</sup>Under section 1(3) b of HOTA including, "any expenses or loss of earnings incurred by a person so far as is reasonably and directly attributable to his supplying an organ from his body." See also Circular No. 308 of 7 September 1989 On the Arrangements for The payment of Costs and reimbursement of expenses Incurred by the Removal from Living Donors of Human Organs or Bone Marrow Intended for Transplantation.



earnings as a matter of right<sup>140</sup> but does not consider other donor costs. A number of laws refer to donor expenses but leave it to statutory interpretation as to whether this includes lost earnings (see e.g. Northern Territory,<sup>141</sup> South Australia,<sup>142</sup> Tasmania,<sup>143</sup> Western Australia<sup>144</sup> and Tunisia<sup>145</sup>). Some adverse consequences, including discrimination in obtaining life insurance<sup>146</sup> and protection from employment dismissal on grounds of being a donor would not be covered by a 'lost expenses and earnings' provision and need specific legislative protection against.

While a donor could expect to be compensated for the consequences of negligent medical practice (s)he might also reasonably want to be compensated for any physical harms that were an unexpected consequence of the donation whether their had been negligence or not. In order to give effect to this wish legislative provision is required - either within transplant legislation or within the context of a no-fault liability compensation scheme. Examples of provision in transplant law include Slovenian law which makes provision for compensation of donor physical harms (free medical treatment and indemnity according to the rules of invalids insurance)<sup>147</sup> as does the Belarus draft law.<sup>148</sup> Portugal's law provides for the donor to be compensated for any injury suffered, irrespective of whether there has been any misconduct,<sup>149</sup> the transplantation centre is required to take out insurance for the donor<sup>150</sup> (interestingly, it has no provision to compensate donors for other financial losses<sup>151</sup>). However, this needs to be read in the light of an earlier provision which prohibits compensating donors for harms which are an immediate result or direct cause of the intervention itself.<sup>152</sup> Consequently, it appears compensation will not be given for harms which

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<sup>140</sup>This has a limited arrangement in place whereby donors having to take a day or more off work receive a daily allowance. Law No. 780 of 25 August 1994 at section 11 (*IDHL*, 1995, 46(1), 33). The daily allowance is in accordance with the provisions of Health Insurance Law (364/63).

<sup>141</sup>The Human Tissue Transplant Act No. 121 of 1979 at section 24(5).

<sup>142</sup>The Transplantation and Anatomy Act 1983 section 35(4).

<sup>143</sup>The Human Tissue Act 1985 at section 27(3).

<sup>144</sup>The Human Tissue and Transplant Act No. 116 of 1982 at section 29(3).

<sup>145</sup>Law No. 91-22 of 25 March 1991

<sup>146</sup>Although in countries such as the United States this is agreed on a National level with the relevant insurance companies.

<sup>147</sup>Law of 1996 at Article 4.

<sup>148</sup>Article 11 of draft law of 1995 (copy held at EUROTOLD).

<sup>149</sup>Section 9(1) *ibid*.

<sup>150</sup>Section 9(2) *ibid*.

<sup>151</sup>Law No. 12 of 22 April 1993.

<sup>152</sup>Section 5(2) *ibid*.



are necessarily the result of the procedure (such as loss of the transplanted material, scar and immediate pain around the removal site etc.) but will be given automatically for non-intrinsic harms resulting from a donation (such as the donor developing chronic uremia, hypertension or septicemia in the removal site). Slovakian law also requires health establishments engaging in organ removal to take out a special insurance policy against liability for damages that may be caused to a living donor during organ removal. This implies that donor may claim for damage but leaves it uncertain as to whether proof of negligence is required.<sup>153</sup>

#### **8.2.5.2. Assurance Provision Within Employment/Social Security Law.**

Since unemployed donors will generally be receiving benefit anyway the fact of donation should have limited adverse financial impact provided that ancillary expenses such as travel are taken care of (e.g. by the hospital). Conversely, a person doing paid work could suffer considerable financial loss consequent upon donation. What are the possibilities for sick pay/benefit for employed donors? There are two critical issues here:

*Firstly* the qualifying conditions for obtaining the benefit and their relationship to living donation. The donor has 'chosen' actions causing an illness. This means the qualification of donors may be under question in some laws and structuring / interpretation of regulations by courts and / or government departments will be critical. Any ambiguity is likely to be resolved in favour of the donor who is acting as a rescuer,<sup>154</sup> and is indirectly saving the state money through donation.

*Secondly* the nature and degree of payment and how this relates to living donors. The extent to which donor's lost earnings are compensated will partly depend on the percentage rate of sick pay vis-à-vis the normal wage. Since donors may be off work for a considerable period of time there will also be a question of whether the length of time sick pay is available for covers the donor's required time off. Required time-off

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<sup>153</sup>Law of 24 August 1994 at section 46(3). *IDHL*, 1995, 46(2), 151-157 at 155.

<sup>154</sup>The legal position of rescuers is discussed briefly in chapter 6.



work varies between donors but a general approximation can be made and matched against sick pay provision within each jurisdiction.

EUROTOLD donor questionnaires asked 27 donors how much time they needed off work. The mean (of 25 responses) was approximately 9 weeks but with a significant minority of donors requiring 3 or more months off (1/6) and a small minority 6 months or more off (1/12). Another study that is useful in this respect is that conducted by Westlie et al. on the Quality of Life in Norwegian Kidney Donors.<sup>155</sup> This study<sup>156</sup> indicates post-donation hospitalisation periods of 7 days or less for 56.7% of donors, 8-14 days for 35.6% of donors, 15-30 days for 6.1% of donors and 31 days or more for 1% of donors. 0.6% of donors did not remember the length of their post donation hospitalisation. Calculating time required off work from these figures is a matter of estimation because living donor nephrectomy is a serious operation and might have incapacitating consequences, such as fatigue, extending beyond the hospitalisation period. For instance, 12.3% of donors in Westlie's study said they had experienced significant medical problems<sup>157</sup> Additionally some time off might be required for pre-operative work. A reasonable assessment might be 9 weeks time-off as an average with most donors covered by a 3 month period.

The time-off work requirements of Norwegian donors in Westlie's study are the best basis available with which to test the adequacy of time-off provision under sick pay regulations globally.<sup>158</sup> Figure 5 looks at employment provisions as they relate to donors based on the above assessment of sick pay needs. An additional factor

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<sup>155</sup>A Copy of this Study can be obtained from the author through The Department of Medicine, Oestfold Sentralskyehus, Fredrikstad, Norway. See also Quality of Life In Norwegian Kidney Donors, *Neph Dial Trans*, 1993, 8, 1146-1150.

<sup>156</sup>Involving 494 living kidney donors in Norway who had donated over a span of 19 years.

<sup>157</sup>However these problems are not necessarily attributable to the donation of an organ indeed it is notable that of unemployed donors in Westlie's study 10.3% were on sick leave whereas 30.5% of the unemployed in the control group were on sick leave. This might suggest that the effects of donation are minimal, although it might be stated that the donors are likely to have started off more healthy than an average member of the population due to the donation screening process excluding more unhealthy persons.

<sup>158</sup>In the EUROTOLD study 9% of donors were in hospital for 0-7 days, 64% from 8-14 days, 27% from 15-30 days. These are similar figures to those for hospitalisation in Westlie's study and would be likely to give rise to similar time-off requirements.



examined in these tables is job security; it being a serious consideration that a donor's "illness" could be used as a justification for the termination of his / her employment.<sup>159</sup>

Figure 5: Country	Sick pay covers normal wages?	Time-off requirements of all donors covered?	Donor qualifies for benefit?	Job security legal rights affected by time off?
Argentina	Fully	Virtually all <sup>160</sup>	Probably <sup>161</sup>	Unstated
Australia	Generally full <sup>162</sup>	Probably with most	Condition unstated	Unstated
Austria <sup>163</sup>	Most-All	Most <sup>164</sup>	Probably <sup>165</sup>	Affected <sup>166</sup>
Bolivia	Varies <sup>167</sup>	Varies	Varies	Unaffected <sup>168</sup>
Brazil	Uncertain	Some <sup>169</sup>	Conditions unstated	Unstated
Bulgaria <sup>170</sup>	70-90% <sup>171</sup>	Virtually All <sup>172</sup>	Probably <sup>173</sup>	Unaffected <sup>174</sup>
Chile	Varies <sup>175</sup>	Unstated	Varies <sup>176</sup>	Unstated
Canada	Most to full <sup>177</sup>	Virtually all	Conditions unstated	Unaffected <sup>178</sup>

<sup>159</sup>The table has utilised the 'bible' for worldwide employment provisions, the International Encyclopedia for Labour Law and Industrial Relations as the foundation for analysis. This is an ongoing work edited by Prof Dr R Blanpain and published by Kluwer.

<sup>160</sup>Blanpain, 2, p124, para 599. Full salary paid for up 3 months when length of service is less than 5 years and for 6 months when more than 5 years, more for workers with family responsibilities.

<sup>161</sup>Ibid, p123, para 594. Incapacity must not have been intentionally provoked.

<sup>162</sup>Ibid, p115, para 235.

<sup>163</sup>Ibid, p93-4, para, 325-334. "Within the limits outlined above, an employee should suffer no financial disadvantage because of illness..Apart from the regular wage or salary, this also includes other benefits of either a normal or exceptional sort, such as commission, incentive- premi.."

<sup>164</sup>Ibid, p94, para 33. Period varies on the employees length of continued service with the same employer but is sufficient for most donors whatever their length of continued service. In the case of the state of Arbeiter less than 5 years entitles the employee to 4 weeks, 5-15 years to 6 weeks, 15-25 years to 8 weeks and over 25 years to 10 weeks. Most donors are likely to have 4-8 weeks or which would be sufficient for some only. The position in Angestellte is even better with up to five years employment entitling an employee to 6 weeks leave, 5-15 yrs to 8 weeks, 15-25 yrs to 10 weeks and over 25 years to 12 weeks. This would cover nearly all donors.

<sup>165</sup>The employee has the right to continued wage payment "where he is not at fault" Page 95, para 336 ibid. There is also a provision which allows short term time-off where the employee, "is prevented from working through no fault of his own for important personal reasons (para 337-338).

<sup>166</sup>P93, para 325 ibid, "there is no protection against losing a job because of illness. Indeed from the point of view of dismissals protection law in general, an employees sickness can be a justification for giving notice." A donor is vulnerable to losing job at least if employed on a more casual basis.

<sup>167</sup>Blanpain, 3, p58, para 32. Social benefits can be voluntarily paid, stem from the labour contract itself or be paid by law.

<sup>168</sup>Sickness results in suspension of the labour contract without legal rights being affected.

<sup>169</sup>Blanpain, 3, p97, para 189. Payment is made: "During short periods of sickness, and also for the first 15 days or more of serious illness."

<sup>170</sup>Art 152 of the Labour code 1951 (social insurance scheme) see Blanpain, 3, p120, para 250.

<sup>171</sup>Amount depending on the length of uninterrupted service as an employee. P121, para 251 ibid.

<sup>172</sup>The only apparent limit is where a worker becomes understood to be permanently incapacitated.

<sup>173</sup>P121, para 254 ibid. A donor may be covered as looking after a family member who is ill.

<sup>174</sup>Art 325 it 9 Labour Code. Termination of contract only possible for illness of long term nature.

<sup>175</sup>Blanpain, 4, p84, para 132. Level of assistance is based on the amount the worker earned in the 6 months prior to his illness.

<sup>176</sup>Entitlement is based on having made 3 months contribution to the social insurance scheme.

<sup>177</sup>Blanpain, 3, p99-100, para 220. Employers duty to compensate is established by the Canadian Supreme Court and in civil law in the case of Quebec. Statutory schemes provide about 60% of wages, employer schemes top this up.

<sup>178</sup>In the situation of temporary illness the Supreme Court has deemed the contract as continuing.



Country	Sick pay covers normal wages?	Time-off requirements of all donors covered?	Donor qualifies for benefit?	Job security legal rights affected by time off?
Denmark	Full <sup>179</sup>	Unstated	Uncertain <sup>180</sup>	Unaffected <sup>181</sup>
Ecuador	Most/all <sup>182</sup>	Probably nearly all	Conditions unstated	Unaffected <sup>183</sup>
Finland	Not stated	Probably most <sup>184</sup>	Probably <sup>185</sup>	Unaffected
France	Probably most <sup>186</sup>	Varies	Varies	Generally unaffected <sup>187</sup>
Germany <sup>188</sup>	Full	Most <sup>189</sup>	Almost certainly <sup>190</sup>	Unstated
Great Britain	Varies <sup>191</sup>	Virtually all <sup>192</sup>	Qualifies <sup>193</sup>	Generally unaffected <sup>194</sup>
Greece	Unstated	Usually most <sup>195</sup>	Probably <sup>196</sup>	Unaffected <sup>197</sup>
Hungary	Full <sup>198</sup>	Unstated	Conditions unstated	Unstated
Ireland	Varies <sup>199</sup>	Varies	Varies	Unstated
Italy	Varies <sup>200</sup>	Varies	Varies	Varies <sup>201</sup>

<sup>179</sup>P 130, para 291 *ibid*. Employee is entitled if (s)he has worked for a minimum of 13 weeks comprising at least 120 hours work. Otherwise will receives social benefits corresponding to the usual wage subject to a ceiling.

<sup>180</sup>P135, para 305. No payment where employee contracts illness through more than slight negligence or intent. Living donor could argue serious illness amongst near family as a justification.

<sup>181</sup>P127, para 282. Where employee contracts illness due to serious negligence or intent the employer has the right to terminate the employment contract without notice. This has to be very serious behaviour however and is unlikely to apply to a compassion situation like organ donation.

<sup>182</sup>Blanpain, 5, p124, para 307. A comprehensive social insurance scheme provides sick pay.

<sup>183</sup>*Ibid*. Law prohibits the termination of contract for a period of illness of not more than one year.

<sup>184</sup>*Ibid*, p91, para 177. The employee must have been working at least one month in order to qualify for benefit. Wide ranging scheme but length of time off it covers is not specifically stated.

<sup>185</sup>If employee willfully or by gross negligence caused the illness no wages will be paid, hence payment of donors is not totally assured.

<sup>186</sup>Responsibility appears to fall to sickness insurance schemes or the employer him/herself where this is specified by collective agreement, coverage can thus vary.

<sup>187</sup>Blanpain, 5, p103, para 194. Additionally; "collective agreements often mention the precise duration of a longer period of absence during which the termination of the contract cannot occur." Such duration varies depending on the seniority of the worker and the particular agreement itself. Donr job security thus depends very much on the particular employment situation of the donor.

<sup>188</sup>In the Federal Republic of Germany rules on sickness govern former GDR also.

<sup>189</sup>Blanpain, 5, p83, para 204. Sickness payment is for 6 weeks.

<sup>190</sup>Para 205 *ibid*. Continued remuneration does not apply where the illness is the employee's fault. Fault is defined as acting "in a manner which is strongly opposed to what a reasonable man would do." Absence for LDT would probably be interpreted as reasonable.

<sup>191</sup>*Ibid* 6, p135, para 243. Not payable for the first 4 days of sickness. Employees do not get normal wage paid under Statutory Sick Pay (they get £54.55) but may do so via a top-up in the employment contract or by custom and practice etc.

<sup>192</sup>28 weeks for any one period of incapacity for work for which eligibility starts immediately.

<sup>193</sup>This has been decided at governmental level.

<sup>194</sup>Dismissal with notice can occur with impunity unless the employee has been with the employer long enough to claim statutory unfair dismissal.

<sup>195</sup>Blanpain, 6, p103, para 205. For one or more years service the employee has the right to one month's remuneration or a half month where employed for less than a year.

<sup>196</sup>*Ibid*. Some uncertainty here as the illness must not be due to employee negligence or fraud.

<sup>197</sup>*Ibid*. Normal notice requirements apply.

<sup>198</sup>*Ibid*, p118.

<sup>199</sup>*Ibid*, 7, p112, para 244. In Ireland most employees have a contractual scheme (express or implied by custom and practice). Schemes vary but in most donor illness is likely to be short enough to be covered for its duration, usually at basic or average pay. If there is no contractual scheme or the donor is unemployed disability benefit is payable from the 4th day of absence onwards. From the 14th day a pay related supplement is given.

<sup>200</sup>*Ibid*, 7, p84, para 164. Sick pay is often payable by the employer - schemes vary according but are generally fairly comprehensive, qualifying conditions vary.

<sup>201</sup>Varies according to collective agreement. Workers on trial do not usually have protection.



Country	Sick pay covers normal wages?	Time-off requirements of all donors covered?	Donor qualifies for benefit?	Job security legal rights affected by time off?
Libya	Probably most <sup>202</sup>	Probably with most	Conditions unstated	Unstated
Luxembourg	Full <sup>203</sup>	Virtually all <sup>204</sup>	Conditions unstated	Unaffected <sup>205</sup>
Malaysia	Full <sup>206</sup>	Virtually all <sup>207</sup>	Conditions unstated	Unstated
Mexico	Full <sup>208</sup>	Some <sup>209</sup>	Conditions unstated	Unaffected <sup>210</sup>
Morocco	Varies <sup>211</sup>	Varies	Uncertain	Vulnerable <sup>212</sup>
New Zealand	Usually most <sup>213</sup>	Varies	Uncertain	Generally unaffected. <sup>214</sup>
Nigeria	Varies <sup>215</sup>	Varies <sup>216</sup>	Uncertain	Generally unaffected <sup>217</sup>
Panama	Uncertain	Some <sup>218</sup>	Conditions unstated	Generally unaffected <sup>219</sup>
Pakistan	Probably full <sup>220</sup>	Virtually all <sup>221</sup>	Varies <sup>222</sup>	Unstated
Peru	Some <sup>223</sup>	Virtually all <sup>224</sup>	Conditions unstated	Unstated
Philippines	Varies <sup>225</sup>	Some/most <sup>226</sup>	Conditions unstated	Generally unaffected <sup>227</sup>
Poland	Usually 75-100% <sup>228</sup>	Virtually all <sup>229</sup>	Conditions unstated	Unstated

<sup>202</sup>Blanpain, 8.

<sup>203</sup>Ibid, 8, p111, para 209. Subject to a ceiling of 5 times the minimum salary.

<sup>204</sup>Benefit is payable for 52 weeks.

<sup>205</sup>An employer generally cannot terminate a contract during a period of illness

<sup>206</sup>Ibid, 8, p48, para 53. Full pay is given.

<sup>207</sup>Ibid. Entitlement for 14 days in each year if the employee has served the employer less than 2 years (18 days for 2-5 yrs, 22 days for 5 yrs+). It is for 60 days in cases requiring hospitalisation.

<sup>208</sup>Blanpain, 8, p100, para 367.

<sup>209</sup>Ibid. Illness disabling the worker appears to result in a social security entitlement of one months pay extendable by twelve days for each year of service.

<sup>210</sup>Blanpain, 8, p101, para 371. The employee has the basic right to return to work after illness.

<sup>211</sup>Ibid, 8, p76, para 170. Extent/availability of payment varies according to contract.

<sup>212</sup>Ibid, 8, p77, para 176. Employer entitled by law to terminate contract in cases of illness.

<sup>213</sup>Ibid, 9, p102, para 162. Varied employer schemes exist usually via collective agreement, they do not usually give payment for the first day of illness. There is also social security sickness benefit - if it is known in advance that the period of incapacity will be 3 weeks or more the benefit can be paid from the day following the cessation of wages otherwise it will be paid from the eighth day of incapacity or the day following cessation of the wages whichever is the later. Additional benefits are paid to those of limited income and cash.

<sup>214</sup>Ibid, p106, para 173. Protracted (not temporary) illness may frustrate an employment contract.

<sup>215</sup>Ibid, p97, para 167. The great majority of contracts, especially those influenced by collective agreements provide for sickness benefit. There is an optional national fund also.

<sup>216</sup>See above.

<sup>217</sup>Ibid, p95, para 163 ibid. Longer term illness can frustrate the contract. Frustration is unlikely to apply in the relatively short absences generally required for living donation.

<sup>218</sup>Ibid, p99, para 274. Sick pay is given for 12 hours for every 26 days served or 144 hours per year. Social security also exists. Any shortfall after combining these has to be met by 'eating into' holiday entitlement.

<sup>219</sup>Ibid, p99, para 274. The contract can be suspended for up to 6 months in cases of illness.

<sup>220</sup>Blanpain, 9, p161, para 466. Payment takes effect from the first day of illness.

<sup>221</sup>Ibid. Sickness leave can be up to 121 years per year.

<sup>222</sup>Ibid. Benefits are only payable if 90 days of contributions have been paid.

<sup>223</sup>The employer has an obligation to continue to fully remunerate for the first 20 days of sickness. At the 21st day onwards the worker receives illness benefit from the Social Security Institute. Some donors would be fully covered within the 20 day period but some might have to go on to social security which may not provide full compensation.

<sup>224</sup>Ibid.

<sup>225</sup>Blanpain, 10, p124, para 387. The employer is not legally required to provide sickness benefit but employees in most companies have it. Social security also provides benefits.

<sup>226</sup>Where provision exists it varies the common practice is to grant sick leave of 15 days with pay after at least one year of service. Social security operates after this point.

<sup>227</sup>However if the illness is longer than 6 months termination of contract is possible.



Country	Sick pay covers normal wages?	Time-off requirements of all donors covered?	Donor qualifies for benefit?	Job security legal rights affected by time off?
Portugal	2/3 or more <sup>230</sup>	Unstated	Conditions unstated	Unaffected <sup>231</sup>
Romania	50-85% <sup>232</sup>	Virtually all <sup>233</sup>	Conditions unstated	Unstated
Spain	60-75% <sup>234</sup>	Virtually all <sup>235</sup>	Conditions unstated	Unaffected <sup>236</sup>
Sweden	90-100% <sup>237</sup>	Virtually all <sup>238</sup>	Conditions unstated	Unstated
South Africa	Full <sup>239</sup>	Some <sup>240</sup>	Conditions unstated	Unstated
Switzerland	Generally all <sup>241</sup>	Almost all <sup>242</sup>	Probably <sup>243</sup>	Unaffected <sup>244</sup>
The Netherlands	70%	Virtually all <sup>245</sup>	Conditions unstated	Unstated
Tunisia	Usually 50% <sup>246</sup>	Nearly all <sup>247</sup>	Probably <sup>248</sup>	Generally unaffected <sup>249</sup>
Turkey	Unstated <sup>250</sup>	Unstated	Conditions unstated	Unstated
Uruguay	70% <sup>251</sup>	Some	Conditions unstated	Unaffected <sup>252</sup>
Venezuela	Most <sup>253</sup>	Probably most	Conditions unstated	Unstated

<sup>228</sup>Blanpain, 10, p112, para 239. Workers employed more than 8 years are entitled to 100% of normal wage, 3 to 8 years entitles workers to 80% while less than 3 years entitles the worker to 75%. There is a one month qualifying period.

<sup>229</sup>Ibid. Benefit applies for 6 months from the first day of sickness / incapacity.

<sup>230</sup>Ibid, 10, p111, para 365. Workers are entitled to the minimum wage guaranteed by law for the sector or 2/3 of his regular remuneration whichever is higher. Social security is also available.

<sup>231</sup>Ibid, p108, para 344 *ibid*. Employee's rights are not to be harmed in any way.

<sup>232</sup>Ibid, p105, para 194. Up to 2 years entitles the employee to 50% of wage, 2-5 years 65%, 5-8 years 75%, over 8 years 85%.

<sup>233</sup>Benefits generally apply from the first day until the end of the illness (maximum of 65 days in any one calendar year for those on fixed term contracts - conditional upon having at least 4 months service during the 12 months preceding the sick leave, or 10 months in the last 2 years.

<sup>234</sup>Blanpain, 11, para 292. This includes average overtime if worked.

<sup>235</sup>Ibid, p77, para 294. Payment continues for 18 months.

<sup>236</sup>Ibid, para 295. Illness only suspends contract and employees have right to return to work after.

<sup>237</sup>Ibid, p98, para 241. A social insurance scheme pays 90% of normal wage and is often topped up to 100% by the employer.

<sup>238</sup>Blanpain, 11, p99, para 242.

<sup>239</sup>Ibid, para 169.

<sup>240</sup>Employee's who work 5 days or less per week are paid sick leave of 30 days per sick leave cycle. Where an employee works more than 5 days this is increased to 36 days. A sick leave cycle is a period of 36 consecutive months. The extent of leave would cover the living donation but the concern is that it would take up most of the entitlement for the whole 3 year cycle. In the first 12 months a person working 5 days or less per week is only entitled to paid sick leave at the rate of one working day for every 5 weeks of employment completed (the rate is a day / month for those working more than 5 days / week).

<sup>241</sup>Blanpain, 11, p116, para 369. Combination of social insurance and an employer scheme.

<sup>242</sup>Ibid p117, para 370. 3 month qualification period, benefit is for 3 weeks for those employed for one year or less. More for longer term employees - around 6 months for very long term employees.

<sup>243</sup>Ibid p116, para 371a. The injury must not have been the employees fault.

<sup>244</sup>Except illness can result in termination where it is of longer duration or in the case of a trial period.

<sup>245</sup>6 weeks or 3 weeks only is it is a small enterprise. This is paid by the employer and after it is exhausted sickness benefit paid by the state takes over at the same rate for a maximum of 46 weeks.

<sup>246</sup>Ibid p60, para 145. Payment according to collective agreement, otherwise by social security payment of 50% of the daily wage, 2/3rds on the 45th day following the beginning of the illness.

<sup>247</sup>Ibid, para 146 *ibid*. In the case of ordinary illness payments of social insurance begin after 5 days and are paid for 180 days this may be extended upon the advice of the medical board.

<sup>248</sup>Blanpain, 11, p60, para 145. The injury "must not have been inflicted intentionally."

<sup>249</sup>Ibid p64, para 161. Termination only justifiable with illnesses of a long term nature.

<sup>250</sup>See Blanpain, 12.

<sup>251</sup>Ibid 12, p154, para 292. 70 % of wages/salary up to three times the national minimum wage.

<sup>252</sup>Blanpain, 12, p153, para 291. The employer must keep the job open for a year.

<sup>253</sup>Ibid 13, p47, para 176. First 3 days not pain unless this is made so by collective agreement.



Those countries where transplant legislation compensates donors also have general principles of employment law that would protect the job security of donors (see e.g. Finland<sup>254</sup> and Belgium<sup>255</sup>). What general points can be brought out of Figure 5? Clearly the provision of sick pay is an overwhelming norm. However, as regards compensation for lost earnings the working donor is typically faced with a financial shortfall that would need to be made up by him/herself or some other source such as the hospital. There are several reasons for the shortfall: Firstly, compensation is typically not at the level of 100% of normal earnings; secondly, donor qualification is not always certain;<sup>256</sup> and, thirdly, a minority of donors are likely to be ill or recovering beyond the duration of time for which sick pay is available.

Most countries in Figure 5 have job security provision solidly protecting workers that would leave living donor job security unaffected by the fact of having time off for donating. A number of other countries require that at least notice be given, often starting from the period of return to work. Since living donation usually involves a relatively short absence it is difficult to see the employer benefitting economically from giving notice, although this might be done if the employer has filled the post with another person. Donors engaged in lower status work are generally more vulnerable through being more replaceable. Legal protection tends to be weaker in cases where workers are only recently employed, temporary or on trial.

### **8.3. Ethics of Financial Exchange in Organ LDT.**

Determining what legislative framework is appropriate for financial exchange in organ LDT involves drawing conclusions as to the *ethical* acceptability of different levels and types of exchange. Systems of exchange of body materials have been the subject of long standing investigation, indeed, it was 25 years ago that Titmuss' landmark study concluded that,

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<sup>254</sup>Illness suspends the contract rather than terminating it.

<sup>255</sup>Blanpain, 2.

<sup>256</sup>The gaps in provision appear to be larger in countries outside Europe.



"the commercialisation of blood and donor relationships represses the expression of altruism, erodes the sense of community, lowers scientific standards, limits both personal and professional freedoms, sanctions the making of profits in hospitals and clinical laboratories, legalizes hostility between doctor and patient, subjects critical areas of medicine to the marketplace, places immense social costs on those least able to bear them - the poor the sick and the inept - increases the danger of unethical behaviour in various sectors of medical science and practice."<sup>257</sup>

The problem has been that much of the investigation has had an apparent attachment to achieving a particular outcome.<sup>258</sup> This has often led to the confusing use of terminology with a simplistic distinction been made between unpaid and paid systems of exchange or, as they are often described, commercial and non-commercial systems. One of the clear objectives of this section is to move beyond the confusion and apparent bias of many studies to develop a systematic and neutral analysis of the ethics of financial exchange. This requires both an analysis of empirical information and ethical values in the light of all the major systems of financial exchange laid out in 8.1.

### **8.3.1. Empirical Data and Its Significance**

#### **8.3.1.1. Current Practice and Different Systems**

Some of the most systematic surveys of financial exchange in transplantation relate to blood donation including Richard Titmuss's landmark study of 'voluntary' and 'regulatorily controlled commercial' blood donation systems. Titmuss's study concluded that a system of commercial exchange was less effective empirically for 4 reasons: It was highly wasteful of blood with the demand and supply position being characterised by chronic and acute shortages; it was administratively inefficient, it was more costly (in the US commercial system "five to fifteen times more costly than voluntary systems in Britain"); *and* tended to lower quality with more likelihood of

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<sup>257</sup>Taken from *The Gift Relationship: From Human Blood to Social Policy*, *Pantheon*, 1971 see also P.Rodriguez, 'Paying Donors and the Ethics of Blood Supply,' *J of Med Eth*, 1989, 20, 31-35.

<sup>258</sup>As noted by Radcliffe-Richards in *Organs For Sale*, Unpublished 1995 Paper, Department of Philosophy, The Open University, Milton Keynes, MK7 6AA, UK.



contaminated blood.<sup>259</sup> Titmuss's study gave rise to considerable comment including an ongoing debate between Arrow and Singer. Arrow maintained that except for the danger of post-transfusion hepatitis Titmuss had not shown the inefficiencies in the US system of blood donation were due to commercialisation.<sup>260</sup> However, Singer shows how Arrow had not even noticed some of the important empirical evidence presented by Titmuss including the proper contrasting of the British voluntary system with the US commercial system and on the link between wastage and commerce.<sup>261</sup> More recently, Fagot-Largeault, in examining the recent crisis in the voluntary blood donation system in France, has suggested that a voluntary system "removes some adverse effects but creates others."<sup>262</sup> Fagot-Largeault's overall finding was that higher health and safety standards resulting from paying blood donors in France.<sup>263</sup> On the other hand, John Keown, in a paper defending the principle of voluntary, unpaid donation in EC directive 89/381 uses the ground of safety as one of five arguments.<sup>264</sup> Keown accepts that "non-payment no more ensures safety than payment precludes safety" but his argument that it is prudent to have a voluntary unpaid system is hard to rebut.<sup>265</sup> His main points are simple but powerful: that it is not possible to screen out problems with 100% success; that viruses are likely to be found in heaviest contamination in commercial blood and plasma products; and that this makes theoretical sense because paid donors tend to be less well off and have a financial interest in concealing any ill health.<sup>266</sup>

However, while payment for blood may attract donors concealing health problems, organ donation is a much more lengthy and involved process and is only likely to attract such donors where the rewards are above what is reasonably obtainable from

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<sup>259</sup>The Gift Relationship, *Pantheon Books*, 1971. Other aspects of this study are discussed later.

<sup>260</sup>Gifts and Exchanges, *Philosophy and Public Affairs* 1972, 343-362 at 361.

<sup>261</sup>Altruism and Commerce: A Defence of Titmuss Against Arrow, *Phil Publ Affairs* 1973, 2, 312-320 at 314.

<sup>262</sup>Fagot-Largeault, Does Non-commercialisation of the Human Body Increase Graft Security, Chapter 2 in Organ and Tissue Transplantation in The European Union, Y.Englert (ed), *Martinus Nijhoff*, 1995 at 13.

<sup>263</sup>Fagot-Largeault, Does Non-commercialisation of the Human Body Increase Graft Security, Chapter 2 in Organ and Tissue Transplantation in The European Union, Y.Englert (ed), *Martinus Nijhoff*, 1995.

<sup>264</sup>The Gift of Blood in Europe: An Ethical Defence of EC Directive 89/381, *J Med Eth* 1997, 23, 96-100 at 98.

<sup>265</sup>*Ibid.*

<sup>266</sup>*Ibid.*



ordinary gainful employment. If incentives increased the number of donors coming forward this could increase organ safety and organ quality by allowing greater clinical selectivity of donors.<sup>267</sup> At the same time empirical studies of non-voluntary donation in centres not having due regard to health and safety has coincided with serious deleterious consequences including: Much higher recipient complication, disease and death rates;<sup>268</sup> increased incidence of manipulation of uninformed donors and outright coercion;<sup>269</sup> discouragement of voluntary-gifting procurement;<sup>270</sup> and in

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<sup>267</sup>Barnett et al., Improving Organ Donation: Compensation Versus Markets, *Inquiry*, 1992, 29, 372-378 at 376.

<sup>268</sup>G.M.Abouna studied 110 Kuwait renal failure patients who had bought organs in the marketplace in such countries as India and the Philippines. His observations of the 59 he saw at the Kuwait Transplant Centre were of inferior quality of care and high complication rate in recipients. 6 patients were known to have died shortly after the operation, 13 to have lost grafts through complications, 14 others to have had serious surgical complications and almost all the remaining patients had come with acute rejection, sepsis or other medical problems. Some had communicable diseases including incidences of AIDS (Commercialization in Human Organs: A Middle Eastern Perspective, *Trans Proc*, 1990, 22(3), 918-92). Al Khader reported results of 20 patients from Saudi Arabia who had gone to certain hospitals in Bombay for commercialized living non-related transplantation (Al Khader et al XI Int.Cong.Trans.Soc.Helsinki, August 1986, Abstract No.S11.4). The numbers of patients who died perioperatively from such perilous engagements was not mentioned by the authors but of those who came back they had been sent away within 3 weeks without adequate referral letters and 95% required admission to hospital in Saudi Arabia to treat rejections and infections or to adjust immunosuppression. A total of 25% had significant renal artery sterosis and fully 40% lost their grafts. One patient acquired Malaria. Similar results come from patients transplanted in Bombay who came from Oman and Dubai (The survey was taken in the period September 1984-December 1986 of 36 patients from Oman 9 died within the period - 6 within the first 100days and the other 3 within a year. At least 2 more had lost grafts and were back on dialysis in Oman. Of 27 patients from Dubai 6 died within 3 months, 4 others had rejections and were back on dialysis (P.J.Morris, *Kidney Transplantation*, 1988, 3rd edition, p72). K.V.Johnny et al. have described a critical shortage of available organs in Kuwait. Conducting a study of 53 patients who have received transplants from unrelated donors, mostly abroad in India they found that from 1985-1990 4 patients had lost their grafts and 3 had died from reasons relating to their transplant. A further 6 had hepatitis B and 7 had tuberculosis (Values Gained and Values Lost in Live Unrelated Renal Transplantation, *Trans Proc*, 1990, 22(3) (June), 915-917). Dr B.N.Colabawalla view of commercial donors from India was that, "most of such donors come from a strata of society where their health and nutrition are already compromised due to economic stringency. Many of these donors may not have been adequately investigated for transmissible diseases and hence pose a danger to the recipient. In this context it is worth noting that of late some reports have documented the occurrence of AIDS in recipients who have received kidneys from this category of donor."

<sup>269</sup>Colabawalla noted the problems of informed consent of Indian donors due to the generally low levels of social and literacy skills. Abouna reported cases of coercion from his study (Commercialisation in Human Organs: A Middle Eastern Perspective, *Trans Proc*, 1990, 22(3), 918-92). News reports have provided evidence of coercion being not uncommon. Mukesh Kosla has reported that, "there are cases of poor patients who have gone for a simple operation having had a kidney removed." (*This Week*, 1989, September 24, 51). The Times of India of 3rd February 1990 reported that 3 young men died at the hands of a 'kidney gang.' Evidence also exists for the practice of buying and selling of children (especially orphans) so that they can be cut up (dead or alive) for their organs. *Sydney Morning Herald*, Wednesday 26 September 1990. See also the United Nations Economic and Social Council Commission on Human Rights 47th session Agenda item 12 report submitted by Mr.Vitit Muntarbhorn on the sale of children.



some cases breach of a basic ethical criteria for LDT that benefit (mainly to the recipient) should outweigh detriment (usually mainly to the donor).<sup>271</sup> Obviously if incentives are to be allowed they must be underpinned by *successfully enforced controls*, such as to ensure donor voluntariness and informedness and high public safety and health standards for donor and recipient. The question is: can controls be successfully enforced in the presence of profit motivated incentive? Roscam Abbing's common sense argument is that profit would be a disincentive to applying controls,

"it is a daily reality that one tends to become lenient on safety standards when trade is involved."<sup>272</sup>

In the final analysis, prudence supports a voluntary, or at least non-profit making, system in organ donation much as it does with blood.

#### **8.3.1.2. Procurement Consequences of Different Systems.**

##### **Profit Based Systems**

While profit making by donors might have deleterious health and other consequences and profit-making by organisers probably would, some commentators have argued in favour of one or both primarily on the grounds that this would be outweighed by significant increases in the available supply of organs.<sup>273</sup> Barnett et al., have argued that a donor and organiser profit based system would "address both the problem of

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<sup>270</sup>Abouna reported an adverse impact on local non-commercial transplantation centres from commercial trade in organs (Commercialization in Human Organs: A Middle Eastern Perspective, *Trans Proc*, 1990, 22(3), 918-92).

<sup>271</sup>The sale of corneas from live donors has become increasingly common and provides a classic example of counterproductivity with one person, usually inspired by a desperate need for money giving up sight in one eye to another person.

<sup>272</sup>Transplantation in the European Union: Management of Difficulties and Health Risks Linked to Donors (ed. Y Englert), *Martinus Nijhoff*, 1995, 99.

<sup>273</sup>See for example R.L.Horton and P.J.Horton, 'Supplying Organs For Transplantation,' *Journal of Health Politics, Policy and Law*, 18(1), 175-188; J.Peters, 'Life or Death: The Issue of Payment in Cadaveric Organ Donation,' *JAMA*, 1991, 265, 1302-1305; H.Hansmann, The Economics and Ethics of Markets for Human Organs, *Yale University*, 56-85; G.Dworkin, Markets and Morals: The Case For Organ Sales, *The Mount Sinai Journal of Medicine*, 1993 (Jan), 60(1), 66-69. Barnett et al., Improving Organ Donation: Compensation Versus Markets, *Inquiry*, 1992, 29, 372-378.



potential donors refusing to donate and that of their never being asked." The altruistic system addresses neither problem while a donor only profit system merely addresses the refusal problem.<sup>274</sup> Barnett et al., potently suggest that in such a free functioning market with procurement firms having an incentive to collect as many organs as profitable and donors profiting from their action "shortages simply cannot persist."<sup>275</sup> Common sense supports their view that there would be a greater drive to procurement. Furthermore, the current trade in living donor corneas which are never donated out of 'altruism' (except where donation is incidental to a therapeutically necessary removal)<sup>276</sup> supports the view that a profit incentive will attract a body of new donors. All other things being equal the potential for improvement would be highest in those areas with a low transplantation rate - where the organs would be most needed.

However, economic variables are an insufficient barometer for predicting human behaviour. With regard to organ donation specifically, most people are unattracted to treating body parts as a commodity. Refusals to donate in an unpaid system are often strongly linked with a reluctance to treat the body as an object.<sup>277</sup> Commodification will overcome the reluctance in some cases but merely amplify it in others. Furthermore, the majority of people are firmly against a profit making system<sup>278</sup> and many could refuse to participate in a profit making system simply

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<sup>274</sup>Barnett et al., Improving Organ Donation: Compensation Versus Markets, *Inquiry*, 1992, 29, 372-378 at 372.

<sup>275</sup>Ibid at p374.

<sup>276</sup>This practice has been fairly commonplace in India for instance.

<sup>277</sup>There is some reluctance on the part of relatives to see the body as just an object with almost two thirds of those in one study refusing to allow donation doing so because they didn't want their relative's body mutilated (Protas J, Batten H, The Willingness to Give: The Public and The Supply of Transplantable Organs, *J Health Polit Policy Law*. This evidence might translate into reluctance to treat the body as a commodity.

<sup>278</sup>A typical public study found 78% of respondents rejecting the idea that families of cadaveric donors ought to be paid for granting permission for cadaveric donation. Amongst the sub group of people unwilling to donate, 65% rejected payment for the families of cadaveric donors. J.Prottas and H.Batten, The Attitudes of the American Public, Report to the Health Care Financing Administration, April 1986. "Hostility to payment is strongest among those in the population presently most willing to donate, about 80% reject any payment system. Among families that have actually donated, an even greater percentage reject the idea of payment. If the percentage of people who refuse to participate in a paid system approaches these numbers, then a market system is a catastrophe. It would result in far fewer organs at far higher cost...even much smaller refusal rates would have a marked impact." J.Prottas, Buying Human Organs - Evidence that Money Doesn't Change Everything, *Transplantation*, 53(6), 1371-1373.



because they did not agree with commodification.<sup>279</sup> The problem is summed up by F.Cantarovich commenting on the Argentine experience of transplantation,

"the attitudes of society towards donation are crucially important for this medical practice.' Only faith in the legal and ethical behaviour of physicians will maintain public support. This trust could be undermined if it became known that unrelated living donors might be used in unethical commercial practices or if cadaveric organs were allocated in an unjust manner."<sup>280</sup>

### Not-for-Profit Reasonable Payment Systems

On current evidence developing a profit-making system would be risky in terms of its procurement consequences but what of systems that are more reflective of reasonable payment for services than profit making? There has been no objection to such systems as regards the payment of staff so why not pay donors a 'mild' incentive such as: a small fixed fee payment representative of effort, inconvenience and harm; or paying the funeral expenses of cadaveric donors;<sup>281</sup> or a health insurance premium reduction plan;<sup>282</sup> or just compensating for expected as well as unexpected physical harm resulting from the operation? Public opinion is less set against such incentives - for instance an NFK/UNOS study found marginally over half of the respondents in favour of 'mild incentives.'<sup>283</sup> Nevertheless, one of the stumbling blocks is the possibility of adverse public reaction amongst those not in favour of incentives. There may be a lack of sophistication in terms of much of the public's ability to distinguish between schemes that are for-profit and those that are for fair payment for service rendered. For example, one survey in the USA where the majority of the 40% of respondents opposing regulated incentive schemes simply stated their major

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<sup>279</sup>See for instance, Austen Garwood-Gowers, To Pay or Not to Pay: That is the Question? An Analysis of the Economic Rights of Donors in D.Price and H.Akveld (ed.), *Living Organ Donation in the Nineties: European Medico-Legal Perspectives*, *EUROTOLD*, 1996, 163-173.

<sup>280</sup>'Values Sacrificed and Values Gained by the Commerce of Organs: The Argentine Experience,' *Trans Proc* 1990, 22(3), 925-927.

<sup>281</sup>T.G.Peters, Life or death: The Issue of Payment in Cadaveric Organ Donation, *JAMA*, 1991, 266, 1302-1305.

<sup>282</sup>H.Hansmann, The Economics and Ethics of Markets for Human Organs, *Yale University*, 56-85 at 63.

<sup>283</sup>Jim Warren (Financial Incentive Controversy Continues, *Dialysis and Transplantation*, March 1993, 156-158).



reason as being opposed to "buying organs."<sup>284</sup> However, there must be a balance struck between respecting public opinion and not being imprisoned by it; the balance may prove to be rejecting profit-making but allowing fair payment provided there are no overriding ethical objections to it. The first step might be adopting Jim Warren's suggestion of adopting a limited incentive scheme in certain areas on an experimental basis.<sup>285</sup> It has been suggested that incentives might hinder attempts to increase participation of community groups already suspicious of the medical enterprise<sup>286</sup> but accompanied by clear explanation to the public non-profit incentives could encourage more prospective donors than the number put off.

Could a limited incentive approach be adopted for cadaveric donation as well living donation? L.R.Cohen has explored the possibility of a futures market where donors choose during their life time what to do with a sum of money given at their death. He says he can, "think of no reason why anyone who now signs an organ donor card would decline to do so if informed that in the process they could also specify their designee (which could be a charity) would receive a sum of money as a result."<sup>287</sup> The problem with this approach is that it is going into the realm of profit making - while a living donor engages in work and endures physical harm that can justify a limited incentive as non-profit making a cadaveric donor's only work was to get and sign a donor card! A consistent approach should be taken and this means excluding profit making unless substantial ethical ground can be found to counterbalance its probable deleterious practical consequences.

#### Assurance Donors Against Their Losses But Not Paying Them For Donating.

The piecemeal state of legal provision in this area has resulted in some donors suffering financial hardship in practice. The study of Westlie et al.,<sup>288</sup> looked at the

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<sup>284</sup>B.Teo, Organs For Transplantation: The Singapore Experience, *Hastings Centre Report*, 1991, Nov-Dec:10-3.

<sup>285</sup>Jim Warren suggests this in the context of the US (Financial Incentive Controversy Continues, *Dialysis and Transplantation*, March 1993, 156-158).

<sup>286</sup>L.M.Sanders et al, The Organ Donation Committee: An Ethically Responsible Approach to Increasing the Organ Donation Rate, *Chest*, 1992, 102(5 November), 1572-1577 at 1573.

<sup>287</sup>L.R.Cohen, A Futures Market in Cadaveric Organs: Would it Work? *Trans Proc*, 1993, 25(1), 60-61. See also L.R.Cohen, *George Washington Law Rev*, 1989, 58(1).

<sup>288</sup>Quality of Life in Norwegian Kidney Donors, *Neph Dial Trans*, 8, 1146-1150.



financial aspects of donating a kidney and found that 17.7% of donors said they had personal expenses associated with donation. In the majority of cases these were met by insurance but a significant minority lost vacation time or had to draw on their own or family financial support (23.6%). Of these a small number were helped out by the recipient (3%). 16.2% of donors replied yes or to a certain extent when asked if the donation caused financial hardship. 6.4% of those who had tried to obtain life insurance had difficulties although the basis of these difficulties may have been health generally rather than in relation to the donation. 3.2% of donors said that the donation had influenced their personal income / career although it was not specified as to how or whether or not this was positive. In terms of procurement it is quite conceivable that without clear assurance provisions some donors will be deterred from donating on economic grounds, this alone is a ground for an integrated, comprehensive system of legal regulation.

### **8.3.2. Ethical Principles and Systems of Exchange.**

#### **8.3.2.1. Distributive Justice.**

What is a just system for distributing organs and what is its significance? A notion in some countries is that quality of health care provision should not depend on one's ability to pay. In practice no system whether nationalised or based on private insurance has fully lived up to this principle; although systems like the NHS have come close there has always been the potential to buy better quality healthcare. Some systems have prided themselves on being privatised with many body parts distributed on an ability to pay basis.<sup>289</sup> The question is what approach to distributing health care and specifically organs is just? One response is to say that if people have 'earned' their money they deserve better services including access to better health care. This would certainly accord with many people's understanding of what fairness is; otherwise people who deserve what they have earned would be paying for those who haven't done anything to deserve this. However, while a cohesive society requires

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<sup>289</sup>As far back as 1993 over 50 artificial body parts were distributed this way in the US as well as a number of natural bodily substances (Gerald Dworkin, *Markets and Morals: The Case for Organ Sales*, *Mt Sin J Med*, 1993, 60(1), 66-69 at 67.



that people do not live off other people's effort, compassion and societal integrity necessitate some degree of mutual support; the evolution of all life requires that people co-operate in assisting the evolution of others as well as themselves (Titmuss recommended a fully socialistic system of distribution and collection of blood partly on this basis).<sup>290</sup> Additionally, inequalities in resources are not just brought about by some people deserving more, they are also brought about by capitalistic exploitation with some getting more than their just deserts by maximising profits from the labour of others.<sup>291</sup> Unethical human behaviour makes it impossible to devise a fair health system so it is a matter of doing the best possible. In the case of organ distribution this does not necessitate a system of free-to-all distribution. Charging very wealthy recipients might be fairer. Equally distributive justice does not necessitate unpaid donation. Indeed it would enhance justice if donors were given a fair sum for effort and inevitable physical harms as well as being assured against losses if this was financed by those who are benefitting from the savings of taking recipients off dialysis (e.g. the state and/or insurance companies).

#### **8.3.2.2. The Slippery Slope.**

Abouna has suggested that,

"it is in the nature of things that whenever a service or medical procedure is carried out solely for commerce or profit and there are vast numbers of patients who are in desperate need of that service, there is often the opportunity and the temptation for deception, exploitation and corruption and a disregard for some of the most cherished moral and ethical values of society."<sup>292</sup>

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<sup>290</sup>R.Titmuss, *The Gift Relationship*, *Pantheon Books*, 1971. Compassion demands that at least some vulnerable members of society are protected e.g. children.

<sup>291</sup> Capitalism undoubtedly plays its part in the transplant regimes of some countries - with transplant professionals earning large amounts of money that are disproportionate with average earnings by several multiples. What is the distinction between this and medical professionals profiting out of organs themselves? From this point of view they can both be aspects of exploitation.

<sup>292</sup>Commercialization in Human Organs: A Middle Eastern Perspective, *Trans Proc*, 1990, 22(3), 918-921.



Abouna specifically talks about a slippery slope where medical professionals are already operating a system of profit e.g. private health care and even a market system for organs where they take money for acting as 'middlemen' etc. What is being examined here is something different - whether a regulatory framework that allows profit making or some less incentives will lead down a slippery slope to objectionable practices. Evaluating slippery slope arguments is, as Raanan Gillon suggests a matter of weighing anticipated benefits of an innovation, and their probabilities, against anticipated harms and their probabilities.<sup>293</sup> In this respect the slippery slope exists as a part of other ethical and empirical questions rather than in its own right.

### 8.3.2.3. Exploitation.

Some commentators have suggested that the profit making and other incentives in organ donation are not exploitative. For instance, Harris has suggested that paying donors is not exploitative because it affords them some money(!)<sup>294</sup> while Radcliffe-Richards almost suggests that not payment is exploitative,

"to forbid the trade, therefore, is to take away what seems the best option open to someone whose position is already so appalling that this is his best option. It is to make the worst off worse off still."<sup>295</sup>

She adds that by stopping the poor donate,

"(w)e can do them nothing but harm by taking options away. The only radical cure for exploitation is the elimination of poverty. Failing that (since we lack either the will or the knowledge to do it), the best thing is not to forbid trade but to subject it to stringent controls: to organise a system that completely rules out all dealings with donors or organs of dubious origin and profiteering by middlemen, to get the highest

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<sup>293</sup>Defending 'the four principles' approach to biomedical ethics, *J Med Eth*, 1995, 21, 323-324 at 324).

<sup>294</sup>September 1991 talk at the Bioethics and Profit Making Conference at Manchester University.

<sup>295</sup>'For Him that Hath Not,' a paper presented at the Munich ESOT Conference on 'Ethics, Justice and Commerce in Organ Replacement Therapy,' Dec 1990. This can be obtained from the Department of Philosophy, The Open University, Milton Keynes, MK7 6AA, UK



price for the organs that the market will bear, to counsel prospective vendors fully about both medical matters and the use of money, and to provide insurance and after care. Provisionally, then, it seems necessary to conclude that this is what we should be doing. We should be eliminating not the trade, but the abuses."<sup>296</sup>

Richards' point can be applied to both the donor and the recipient. However, for the recipient it only holds up for payment systems that enhance procurement (in terms of numbers and quality of organs) thereby promoting the interests of all recipients. Whether or not properly regulated systems paying the donor are exploitative will depend on the context. If a system is devised that pays the donor but damages procurement it is exploitative if one considers the rights of the recipient more important. As earlier noted, there is a very real possibility that systems based on profit-making will have a damaging impact on procurement. A further potential exploitation in profit making systems is exploitation of the donor: *Firstly*, safety standards in the treatment of the donor (including potential use in more experimental situations<sup>297</sup>) may inevitably lower if there is profit making by organisers; *Secondly*, neither profit nor the maintenance of standards applied to voluntary and informed consent can be guaranteed - although whether there would be more exploitation of this kind where a profit-based system is legal than there is at present is questionable; *and thirdly*, even if profit making is restricted to donors there is a danger that the poor be treated as an organ bank with this in itself becoming an exploitative disincentive to providing more solid assistance to encouraging people out of the poverty trap. The fact that the poor are already being used as an organ bank in some areas is partly indicative of how a minority capitalistic interest has treated human and natural resources as means to an end (units for profit<sup>298</sup>) consequently reducing the scope for self-determining, self-sufficient resourcing by the majority. On a global level the appropriate remedial action is to address the exploitation and expropriation and its

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<sup>296</sup>Ibid at p4-5.

<sup>297</sup>Keown's recent blood donation article (The Gift of Blood in Europe: An Ethical Defence of EC Directive 89/381, *J Med Eth* 1997, 23, 96-100 at 98) points out Titmuss' finding of unethical experimentation and plasmapheresis in a commercial system and dangerous frequencies of donation in a recent study (survey of 10,000 plasma donors finding that over 30% donated more than 18 times in a period of only three months - N.B. Paull, Safeguarding Donors: First, Do No Harm, *J Am Blood Res Ass*, 1993, 11 (Spring), table 4.

<sup>298</sup>For an article detailing this process see Balbus, Commodity Form and Legal Form: An Essay on the Relative Autonomy of the Law, *Law and Sociology Rev*, 1977, 11, 571.



causes rather than placing attention on the temporary 'solution' of selling body parts. While this points towards preventing profit-making by donors, any legal responsibilities and sanctions need to be placed on the organisers of transplantation - the donor is merely trying to better him/herself.

A voluntary system can also be exploitative for not paying donors a fair amount for the physical damage and effort involved in donation. The exploitation is doubled where the voluntary system fails to properly assure donors against losses.

### **8.3.3.3. Rights to Donate an Organ for Money and Ownership of the Human Body?**

Some writers have considered the body as a form of property salable in the same way as other essential commodities such as food and shelter.<sup>299</sup> Andrews, who is in favour of profit making for donors and organisers<sup>300</sup> has suggested,

"humans have the right to treat certain physical parts of their bodies as objects for possession, gift and trade."<sup>301</sup>

Whether or not body can be considered "property" and "owned" is largely a technical, legalistic issue. The important question to ask does a person have an ethical right to dispose of it as they please? Blumstein has noted that donor profit making (and by analogy profit making by organisers),

"emphasizes respect for the autonomy of the donor..de-emphasizes paternalism, and strengthens the hand of the individual rather than the family."<sup>302</sup>

Expanding on this theme Radcliffe-Richards states that preventing donor payment,

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<sup>299</sup>See comment "Retailing Organs Under The Uniform Commercial Code," *J.Marshall L.R.*, 1983, 16, 393.

<sup>300</sup>The Body as Property: Some Philosophical Reflections - A Response to J.F.Chidress, *Trans Proc*, 1992, 24(5) October, 2149-2151.

<sup>301</sup>Andrews, "My Body, My Property," *Hastings Center Report*, 1986, 16, 28 at 36.

<sup>302</sup>The Case for Commerce in Organ Transplantation, *Trans Proc*, 1992, 24 (5) at 2190-2197.



"...obviously runs against the fundamental liberal principle that although people's freedom of action may legitimately be curtailed to prevent their harming others, it may not be curtailed to prevent their harming themselves. Anyone who takes this principle to be absolute, as many do, must obviously rule out paternalistic intervention completely.<sup>303</sup>

The limitation of this approach is that regulatory intervention is not necessarily about paternalism in the first place - it can equally be about upholding the reputation of transplantation as based on ethical standards of conduct and protection of prospective recipients (and donors) from potential adverse consequences arising from systems of donor payment that allow profit making. Radcliffe-Richards provides a counter-argument by stating that,

"Even if it is argued that some of the potential vendors are being subtly coerced, or are too ill informed to make rational decisions, the absolute version of the principle can justify intervention only in particular cases. It cannot permit a general prohibition which curtails the freedom of all."<sup>304</sup>

However, it must be questioned whether a payment system, at least one involving profit-making, can successfully maintain levels of respect for informed consent. More potently, the donors rights must not be viewed in isolation but as part of a broader picture involving the rights of those paying for transplantation and the recipient. Those paying for transplantation have a right to expect a system that maximises ethics and benefits and minimises costs (without exploiting those involved). The problem with allowing profit-making is that it would increase costs, potentially reduce ethics and (aside from the direct economic benefit to the donor) not assuredly raise benefits (indeed it might reduce levels of organ quality and procurement). Danger of lower benefits justifies legislative intervention as a cautionary measure; the recipient's right to the most beneficent system is more

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<sup>303</sup>For Him That Hath Not in W.Land and J.Dossetor, *Ethics, Justice and Commerce in Organ Replacement Therapy*, *Kluwer*, 1990.

<sup>304</sup>For Him That Hath Not in W.Land and J.Dossetor, *Ethics, Justice and Commerce in Organ Replacement Therapy*, *Kluwer*, 1990.



important than any donor or organiser interest in selling.<sup>305</sup> In any case what the donor and organisers actually have a right to is not to be economically exploited by profit-making but to obtain payment representing a fair non-profit making payment for services rendered.

#### **8.3.3.4. Altruism and Social Solidarity.**

Proponents of unpaid donation like Titmuss<sup>306</sup> and Keown<sup>307</sup> have emphasised the unquestionable social utility of altruism and social solidarity. From an empirical standpoint these values will no doubt play a central role in unpaid donation, as Keown's review of studies of why people donate blood in an unpaid system has illustrated.<sup>308</sup> In addition, a profit making payment system may damage procurement. However, neither of these conclusions is obviously a reason to favour unpaid donation over a system of reasonable donor payment. Prospective social utility of volunteering must be insufficient grounds for an unpaid donation system - otherwise payment would only be available for the useless or detrimental activities in society!

Why mark out donation for volunteering then? Keown has emphasised the potential deleterious societal impact of paying donors in the form of encouraging a trend toward commercialisation at the expense of social solidarity.<sup>309</sup> However, if paying donors a reasonable amount is fair our paid or unpaid time may be better spent addressing more fundamental reasons for waning social solidarity and altruism such as (capitalistic) exploitation of people and natural resources as almost solely means to an end (units for profit). Otherwise the position of the state becomes hypocritical; on the one hand regulating to push for volunteering in one area and on the other hand being reluctant to intervene to address one of the real causes of exploitation; a global

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<sup>305</sup>It could, however, be realistically suggested that many of the donors are also in a desperate quality of life situation and that given this they are almost as important in the consideration as recipients - see Radcliffe-Richards, *Organs for Sale* 1995. However it has already been suggested that organ sale, at least where involving profit-making is not a constructive way of dealing with poverty.

<sup>306</sup>*The Gift Relationship*, Pantheon Books, 1971

<sup>307</sup>*The Gift of Blood in Europe: An Ethical Defence of EC Directive 89/381*, *J Med Eth* 1997, 23, 96-100 at 96-7.

<sup>308</sup>*The Gift of Blood in Europe: An Ethical Defence of EC Directive 89/381*, *J Med Eth* 1997, 23, 96-100 at 96-7.

<sup>309</sup>*Ibid* at 97.



economy where consumption and profit are placed above the notion of economic endeavour as a service to real human needs.

#### **8.4. Conclusion.**

Legal prohibition of commercial trade in organs is becoming almost universal within countries with the technological capacity to undertake transplantation. Limitations include some laws only focusing on preventing payment of the donor and / or recipient and most not excluding advertising. The regimes in Hong Kong, India and United Kingdom, which are some of the most recent pieces of transplant legislation, provide a reasonable model for comprehensive prohibition of trade that could be adopted more widely.

Despite assertions that the level of trade in organs has been exaggerated by the media<sup>310</sup> trade is clearly extensive globally. Whether or not this means legislative prohibition of trade should be developed is both a practical question and an ethical one. Practically, establishing a correlation between legal prohibition and a reduction in commercial dealings is crucial; without it the law is paper tiger. Kishore arguing that scarcity breeds crime, has suggested that experience has shown that laws preventing commercialisation are breached and circumvented "and do not provide the answer."<sup>311</sup> In many countries banning the trade it continues to thrive on a significant scale,<sup>312</sup> essentially because of global organ shortage combined with financial incentive to participate in a 'black market' (and ultimately as the result of adopting transplantation as an approach to dealing with organ disease). On the other hand, common sense would suggest law is likely to have some deterrent impact.

The dominant vision underlying transplant law is the conscious or unconscious pre-eminence given to the notion of donation-as-voluntary-gift. Donors are not

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<sup>310</sup>See e.g. H.Kreis, Chapter 10 in *Organ and Tissue Transplantation in the European Union: Management of Difficulties and Health Risks Linked to Donors*, Y.Englert (ed), *Martinus Nijhoff*, 1995. A review of this book is produced by A.Garwood-Gowers, *IDHL*, 1996, 47(1), 126-7.

<sup>311</sup>Organ Donation: Consanguinity Vs Universality - An Analysis of Indian Law, Manuscript with EUROTOLD.

<sup>312</sup>For instance Argentina, Brazil, Russian Federation and India. Some national legislation such as the Human Organ Transplants Act 1989 (section 1) prohibits it's nationals from buying an organ abroad but most laws do not. However this and other limitations in organ can only be a partial explanation for continued trading.



compensated for physical harms that are a normal consequence of donation (e.g. scarring, pain, inconvenience) or for time and effort expended because this would mean a shift from volunteering (unpaid work and gift) to gainful employment. The not-for-employment approach is questionable but what is more serious is that while donors will get free medical care in relation to donation and its consequences (some laws make this explicit - e.g. Portugals law states that donors have the right to medical care until completely recovered<sup>313</sup> with transplantation centre insurance being mandatory partly for this purpose<sup>314</sup>), they do not, as already seen, get comprehensive assurance against negative economic consequences from donation. Consequently a donor can end up in a far worse position than an ordinary volunteer - having to endure a 'double whammy' of physical harm and economic loss.

It has been argued that assuring against physical harm might create a falsely amplified impression of the risks of donation in the minds of potential donors. However, this seems unlikely given donors at present tend to have an unrealistically low perception of risks<sup>315</sup> and given compensation for physical harm could unobtrusively be part of a wider package of assurance clarifying and expanding on Article 9 of the Council of Europe's Resolution (78)29 which includes the statement that, "...the donor, or potential donor, must be compensated independently of any medical responsibility, for any damage sustained as a result of a removal procedure or preceding examination, under a social security or other insurance scheme." There are also several positive reasons for integrated, comprehensive donor compensation provisions including the fact that it may save money and improve quality of life by encouraging more people to donate and the fact that it shows respect to the donor right not to lose out when doing such an important public service.

Beyond compensation for loss the ethics of financial exchange is more difficult to determine, especially because reliable evidence is limited. Introducing a profit-making system, particularly for organisers but also for donors is likely to have negative empirical consequences. It is more ethical and less risky to introduce a

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<sup>313</sup>Section 9(1) *ibid.*

<sup>314</sup>Section 9(2) *ibid.*

<sup>315</sup>See chapter 9.



reasonable payment system on an experimental basis in some areas. The likely damage of a profit based system is enough to justify prohibition.



## Chapter 9 Research With Donors and Recipients in LDT.

### 9.1. Introduction.

Research with living donors, recipients and their families, which has been conducted over a period of 30 years, has focused on the perceptions, processes and effects of LDT largely to derive data about the clinical, attitudinal and motivational aspects of the LDT process. This chapter had a slightly broader aim of highlighting practice relevant to the ethical and legal issues in LDT discussed in the 6 preceding chapters. There were 5 particularly significant areas of consolidation and expansion on existing research:

- *Firstly*, problems with 'patient' medical decision making processes have been identified in the general psychological literature and partially verified with regard to donors.<sup>1</sup> However, this research was needed to refocus attention and contemporise evaluation based on the fact that only a few studies have been conducted more recently than the 1970's;<sup>2</sup>
- *Secondly*, the European focus of this research builds on a currently sparse European profile of donor-recipient research most of which has been conducted in the United States;
- *Thirdly*, this research pioneers a multi-national approach to donor recipient interviewing - acting as a model for direct cultural and societal comparisons between different centre and national LDT participant experience;
- *Fourthly*, this research focuses on professional information disclosure and communication aspects of the LDT consent process. Aside from Wrestle et al.'s Quality of Life of Norwegian Donors Study<sup>3</sup> this has been a fairly neglected area of research;<sup>4</sup> *and*
- *Fifthly*, this research develops the theme of consideration of the financial consequences of donation which really only began in earnest with Westlie et al's research in the early 1990's.<sup>5</sup>

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<sup>1</sup>See chapter 6.

<sup>2</sup>E.g. L.Westlie et al., Quality of Life in Norwegian Kidney Donors, *Neph Dial Trans*, 1994, 8, 1146-1150.

<sup>3</sup>L.Westlie et al., Quality of Life in Norwegian Kidney Donors, *Neph Dial Trans*, 1994, 8, 1146-1150.

<sup>4</sup>Most studies are focused around donor and recipient psychological and physical health - with an angle on the decision-making process but not the information that was given.

<sup>5</sup>L.Westlie et al., Quality of Life in Norwegian Kidney Donors, *Neph Dial Trans*, 1994, 8, 1146-1150.



## **9.2. Research Methodology.**

The method of investigation with donors and recipients was interviews using a questionnaire format. As stated in the application for funding to the European Commission,

"...this interview method has been chosen to allow the full context of the decision making process to be expounded and for strength of feelings and attitudes to be able to be fully expressed, an essential facet of the research."<sup>6</sup>

### **9.2.1. Techniques Utilised.**

The earlier half of the research was conducted on a tape recorded basis interviewing donors and recipients based on a semi-structured questionnaire. This was similar to the approach of Fellner and Marshall's 1968 12 donor study.<sup>7</sup>

Donor-recipient issues include deeper concerns such as motivational issues not amenable to being fully understood through fully structured multi-choice questionnaires. Semi-structured interviews allowed donors and recipients more freedom to focus on areas most important to them. Counselling abilities<sup>8</sup> supported a more neutral and phenomenological approach designed to facilitate in-depth researcher and participant reflectivity to the issues. In the second half of the research a fully structured questionnaire was used (administered face-to-face). This questionnaire had the advantage of obtaining more quantitatively consistent data.

### **9.2.2. The Sequence of Investigation.**

#### **9.2.2.1. Questionnaire Development.**

Initially the questionnaires were developed by David Price and I with assistance from Professor Ronnie Mackay, Anne Simpson, former transplant co-ordinator at Leicester

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<sup>6</sup>EUROTOLD (unpublished).

<sup>7</sup>"conducted in an open ended fashion with a pre-arranged questionnaire..tape recorded." Twelve Kidney Donors, *JAMA* 1968, 206(12), 2703-2707 at 2703.

<sup>8</sup>During the course of the investigation I gained a counselling qualification which has since been supplemented by counselling experience. The approach adopted was person (see Appendix 4).



General Hospital, and Professor Peter Donnelly, former transplant surgeon at Leicester General Hospital and EUROTOLD project leader.<sup>9</sup> Expert psychological collaboration was provided by Leicester General Hospital staff including Christine Cordle a clinical psychologist. Dr Arnt Jacobsen of the Oslo Transplant Centre<sup>10</sup> provided external clinical consultancy. The pilot study involved interviewing former donors and recipients of the Leicester General Hospital's transplant centre during the years of 1992 and 1993. Hospital Ethical Committee approval was granted for this.

A set of questions was developed for both donors and recipients. The first set of questions<sup>11</sup> was used in both the Leicester and Oslo samples. A few developments were added for interviews in Dublin.<sup>12</sup> In these 3 centres a total of 58 participants were interviewed (28 donors and 30 recipients).

During 1993 the EUROTOLD Project gained funding from the European Commission and the questionnaire a second method of fully structured interviewing was utilised.<sup>13</sup> This new method gave multiple choices to recipients with answers being filled in on the questionnaire itself. EUROTOLD's PECO collaborators in Slovakia, Slovenia, Romania and Poland conducted interviews using this method with a total of 102 participants being interviewed (48 donors and 54 recipients). The results of these interviews were collated and analysed by myself and are presented in this chapter.

With Albania having no transplant programme at present Myftar Barballushi was inspired to develop a questionnaire for Albania on 'Attitudes Toward Transplantation of the Families of Albanian End Stage Renal Failure Patients'.<sup>14</sup> 51 participants were interviewed. The results of this questionnaire were collated and analysed by myself and again are presented in this chapter.

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<sup>9</sup>Alison Lea and Susannah Carr, successive EUROTOLD scientific co-ordinators, assisted in later revisions.

<sup>10</sup>Part of the National Hospital of which he is the director.

<sup>11</sup>Figures 1&2 Appendix 2.

<sup>12</sup>Figures 3&4 Appendix 2.

<sup>13</sup>Figure 5 Appendix 2. EUROTOLD's scientific co-ordinator at the time (psychologist Alison Lea) contributed strongly to these new developments along with other members of the EUROTOLD group such as myself and David Price. External clinical consultancy was provided by EUROTOLD participants across Europe.

<sup>14</sup>This questionnaire was adapted from the donor- and recipient questionnaire simply because no LDT's have occurred in Albania.



### **9.2.2.2. Centre Selection.**

Centres were chosen for conducting the interviews based on existing collaborative links. Some centres refused the opportunity to collaborate in interviewing, primarily because of the time commitment involved.<sup>15</sup>

One issue that the research raised was whether centre selection produced any bias. Whilst only Oslo and Leicester have significantly high rates of LDT p.m.p,<sup>16</sup> some bias might be expected through the fact that all participating centres had a positive attitude towards LDT and through a degree of selectivity exercised over participant choice.<sup>17</sup>

### **9.2.2.3. The Programme for Interviewing.**

The pattern of the 211 interviews was as follows:

- **Leicester Transplant Centre** (Leicester General Hospital) 1992-3 22 participants interviewed (12 recipients 10 donors)<sup>18</sup> most at home, some at the hospital;
- **Oslo Transplant Centre** (National Hospital) Summer 1992<sup>19</sup> 26 participants (13 recipients 13 donors) interviewed at the hospital;

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<sup>15</sup>One centre was activated to discuss the development of it's own living donor protocol as a result of receiving the questionnaire. Another was willing but the time scale remaining was too limited to gain the necessary prior ethics committee approval and conduct the research.

<sup>16</sup>Or indeed, a high percentage of LDT's out of the total number of transplants conducted *and* Albania does not conduct transplants and the Eire centre in Dublin has recently only conducted LDT's in exceptional circumstances (e.g. twins).

<sup>17</sup>There were three elements of selectivity of participant choice predisposing the research to bias: *Firstly*, in some cases (particularly Oslo) a certain degree of selectivity was used in choosing research participants (by the hospital nephrologist in the case of Oslo). This was primarily done to produce a varied spread of participants including some non-genetically related pairs (6 spousal and 1 brother in law pair out of 13 pairs in Oslo) but may also have consciously or unconsciously involved exclusion of certain donors and recipients based on sensitivity to their needs which might have produced bias (e.g. less of a tendency to put forward donors and recipients in cases of graft loss or death of one of the pair); *secondly*, selectivity was applied in terms of geographical and general accessibility (the ability of donor's and recipients to meet-up for interview). It might be expected that those who were unable to be interviewed for this reason would tend as to have more problems with the donation process than their interviewed counterparts (e.g. more financial costs from travel and lost time, more stress); *and thirdly*, bias may also have entered inevitably through some donors and recipients choosing not to participate precisely because of a less positive attitude to their experience.

<sup>18</sup>In collaboration with Peter Donnelly and Anne Simpson respectively former transplant surgeon and former transplant co-ordinator at Leicester General Hospital.

<sup>19</sup>In collaboration with Arnt Jacobsen now director of the National Hospital and with two nurses providing oral translation in the interviews.



- **Dublin Transplant Centre (Beaumont Hospital) Spring 1993<sup>20</sup>** 10 participants (5 recipients and 5 donors) were interviewed at the hospital;
- **Poland (from the base of the Warsaw centre) 1995-1996<sup>21</sup>** 45 participants were interviewed (21 donors and 24 recipients);
- **Slovenia 1996<sup>22</sup>** 46 participants were interviewed (24 donors, 22 recipients);
- **Romania 1996<sup>23</sup>** 5 participants were interviewed (5 recipients);
- **Slovakia 1996<sup>24</sup>** 6 participants were interviewed (3 donors and 3 recipients); *and*
- **Albania 1995** interviews conducted with 51 participants who were members of families of ESRF patients.<sup>25</sup>

In the case of the semi-structured interviews results were transcribed in detail. A distillation was then produced for this chapter with the aim of retaining a unique flavour of interviews as well as drawing broader conclusions related to LDT ethical and legal issues addressed in the PhD so far. Results from the questionnaires used by Slovakia, Slovenia and Romania were inscribed on the questionnaire and form a more standardised body of data which lent itself to a more exclusively statistically oriented write-up. Albanian results were written-up in similar fashion.

### **9.3. Substantive Findings.**

#### **9.3.1. Benefit and Detriment in LDT.**

##### **9.3.1.1. The Donor**

###### **Self-esteem**

This study somewhat bore out the conclusion that LDT can positively benefit a donors self-esteem, although overall the benefits are not that marked with only one donor stating

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<sup>20</sup>In collaboration with Dr Murphy a transplant surgeon and the two transplant co-ordinators.

<sup>21</sup>Interviews were conducted by Professor Rowinski's team and analysed by myself.

<sup>22</sup>Interviews conducted by Igor Luksic (a EUROTOLD PECO participant in Slovenia) and analysed by myself.

<sup>23</sup>Interviews conducted by the Romanian PECO team and analysed by myself

<sup>24</sup>Interviews conducted under the co-ordination of Barbara Grantnerova, a Slovakian nephrologist with analysis by myself.

<sup>25</sup>Under the co-ordination of Dr Myftar Barballushi nephrologist at the Tirana Hospital using a questionnaire he adapted for the purpose. All but two (grandmothers) of those interviewed were immediate nuclear family members (blood and spousal relationships) of an ESRF patient. The questionnaire was analysed by myself.



that they felt very much higher after donation. 21 donors in the Polish sample responded to the question as to how they thought of themselves post-donation compared with self perception prior to donation. 5 donors said they thought of themselves a little more highly now, 16 donors said there was no difference. The recipients view of donor self-perception was more marked - 5 recipients feeling that their donors viewed themselves as having very much higher self-esteem, 2 a little higher and 10 no difference. The Slovenian sample produced very similar results; 1 person thought of themselves "very much higher," 5 "a little higher" and one, suprisingly, "a little lower." Recipients also generally thought the donor's self-perception was unchanged (16 "no different," 5 "a little higher," 1 "very much higher"). Similar results were obtained in Romania<sup>26</sup> and Slovakia.<sup>27</sup>

### Donor-Recipient Relationship.

Another of the benefits of LDT for the donor could be that it can build a closer relationship with the recipient. Greater closeness was found in a significant number of interviews and is probably not simply attributable to the passage of time. 18 Polish donors said that there was no change in their relationship with the recipient as compared with the position pre-donation/transplant, whilst 3 donors said that it had improved.<sup>28</sup> This picture of largely unchanged but occasionally improved relationships was confirmed by the recipients; 21 saying the closeness of their relationship to the donor was unchanged post-donation whilst 2 said it had improved. Most Slovenian donors (14 of 24) assessed their relationship with the recipient as close and in most instances (17 of 24) unchanged after donation (5 improved, 1 greatly improved and 1 got slightly worse). Slovenian recipients had a similar perspective.<sup>29</sup> The small Romanian sample, on the other hand presented a more positive picture of change from the recipients perspective; all recipients expressed having extremely / very or fairly close relationships with the donors and in 3

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<sup>26</sup>In the Romanian interviews most recipients felt the donor's self-perception was unchanged (4 out of 5 - the fifth "a little higher").

<sup>27</sup>Donor self-perception and health were unchanged. 1 recipient felt a donor had "a little higher" self perception

<sup>28</sup>In 90% of instances the donors described themselves as being very close to the recipient even before the donation/transplant.

<sup>29</sup>With this recipient assessments of the relationship before donation were divided between very close (11) and fairly close (10) with little change after donation (17 "didn't change," 4 "improved," 1 "got slightly worse"). Interestingly in 4 Slovenian donors and 2 recipients stated that donation caused family conflict; reasons for this were not clearly illuminated. Although the recipient in one interview commented that both parents wanted to donate and in another interview the recipient stated that the donor's wife had been worried about the donor donating



out of 5 cases this had improved after the donation.<sup>30</sup> In 7 out of the 13 Oslo interviews<sup>31</sup> the participants stated that they had a close relationship with each other which in 3 of these cases was closer after the operation.<sup>32</sup> The quality of donor recipient relationship was commented on positively in most Leicester interviews<sup>33</sup> the typical response being that the participants felt they were closer as a consequence of sharing the experience of LDT.<sup>34</sup> All the Slovakian donors viewed themselves as very close to their recipients and that this relationship was unchanged after the operation.<sup>35</sup>

### Physical Health

Insufficient interviews were conducted to derive much information about physical detriment to donors - EUROTOLD has developed the Donor Health Registry<sup>36</sup> to explore this aspect more thoroughly. Nevertheless, donor quality of health issues were discussed in a number of cases. The most surprising feature was that some donors actually felt their health had improved after donation!<sup>37</sup>

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<sup>30</sup>In 2 cases remaining unchanged.

<sup>31</sup>6, 7, 8, 10, 11, 12, 13.

<sup>32</sup>8, 12 and 13. For example, the donor in interview 13 stated his relationship with the recipient was closer, a feeling echoed by the recipient who stated that, "we talk more about feelings now."

<sup>33</sup>1 and 2, 3, 4 and 5, 6 and 7, 8 and 9, 12 and 13, 14, 15 and 16.

<sup>34</sup>Closeness was also examined by many of the recipients from their perspective. In one Leicester interview (15 and 16) the recipient remarked that he felt slightly further apart from the donor but "not to any effect really." In a further interview (17 and 18) the recipient felt that he and the donor had never been close and he wasn't able to visit because of his discomfort with being a passive smoker - The recipient said he would "love to be closer to the donor." Interestingly the donor felt that her family never smoked in his presence; there was clearly a degree of breakdown in communication.

<sup>35</sup>No family conflict had been caused in donation.

<sup>36</sup>See chapter 9.

<sup>37</sup>Polish donors were asked how their health had changed since donation. 4 stated that it had got slightly better, 13 said it was the same and 4 said that it had got slightly worse. Amongst the sample of Slovenian donors health was largely unchanged, although 5 participants stated that their health had "worsened slightly" (details included less energy fatigue, more nervous and slight elevation of blood pressure) and 1 that it had "improved slightly" as a result of donating the kidney. In interview 1 and 2 of the Leicester interviews the donor expressed problems with sepsis of the wound site, similar problems were expressed by the donor in interview 12 and 13. The donor in interview 4 and 5 discussed temporary discomfort and sleeping difficulties after the operation. The donor interview 15 and 16 discussed still getting twinges. In the Oslo interviews, the donor in interview 3 said he picked up a hospital virus afterwards. In one interview the donor said there could have been more check - up's and a six month sick note was not long enough (11). In interview 11 the donor said her recovery had been slow and as yet incomplete, but added that this might be partly her age. In interview 10 the donor said that he had pains for quite a long time from his ribs being removed. In interview 9 the donor stated that he had a cold and stomach cramps for a while and could not sleep on the side where the incision was made. One donor could not walk for a time after the operation and was exhausted. There were no long term effects however. the donor said that the pain of one of the rib bones being removed took some time to dissipate. No health complications were mentioned amongst the Dublin donors.



### **9.3.1.2. The Recipient.**

While the sample was not significant enough to draw out quantitative conclusions on recipient health a few interesting points can be highlighted. In only one case was clear unhappiness expressed about receiving an LDT because of health problems;<sup>38</sup> interestingly the donor in this case was still happy with his decision. Several recipients in the Oslo interviews specifically spoke of side effects of drugs with one saying that were "tremendous."<sup>39</sup> However, at the same time, several also commented to the effect that it was a new lease of life.

Some psychological strains were reported including strain on the spousal relationship in one interview<sup>40</sup> where there had also been sexual problems after the transplant in the spousal relationship. Sexual problems were also reported in two other interviews.<sup>41</sup> This might be an area where practitioners should give warnings prospective recipients.

### **9.3.2. Disclosure and Informedness.**

#### **9.3.2.1. The Donor**

##### **Disclosure**

In general the picture of the quality of disclosure to donors is somewhat mixed. At the one extreme there were 4 donors who said they were not informed about any risks (2 in Slovenia and 2 in Poland) plus a number who expressed negative overall picture of disclosure - for instance in the Leicester sample one donor felt that he did not have a clear perception of the facts of risks being involved, "I don't remember anybody saying anything about risks um, no they just told me straightforward this is what will happen and if they though there was any risk at all they wouldn't have done it..."<sup>42</sup> Several donors also expressed more specific concerns such as: not being informed about the

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<sup>38</sup>Leicester interview 12 and 13.

<sup>39</sup>13.

<sup>40</sup>Leicester interview 3.

<sup>41</sup>This was also the case with the recipient's relationship with his wife in Leicester interviews 15 and 16 - although possibly in this case due to a dysfunctional relationship than a straightforward physiological consequence of the transplant. In the Oslo interviews one recipient had sexual problems associated with transplant.

<sup>42</sup>4 and 5.



possibility of sepsis at the incision site;<sup>43</sup> that information concerning "whether or not I would be O.K. on one kidney could have been better;" and that they could have been told more about the possible impact of the donation on their sex life.<sup>44</sup>

On the other hand in the majority of interviews the overall assessment of disclosure was positive. In Oslo 8 out of 13 donors<sup>45</sup> felt the quality of information was wholly positive, with such phrases as "very good information" and "I felt the doctors told me everything." In the Leicester interviews one donor stated, "I do believe the doctors really tried to make you aware"<sup>46</sup> and another said, "they went to a great deal of trouble to ensure that I knew what was going to happen and I felt quite happy about that."<sup>47</sup> In Dublin the comments of the 5 donors about disclosure were all positive.<sup>48</sup> Some Slovenian donors were aware of being told more than one risk. The most common risks donors were aware of being told about were surgical complications (6) and possible graft failure (2). Polish donors typically mentioned being informed of one or two of the risks of donation - risks mentioned included; surgical (5), risk of living on one kidney (3), post-operative complications (1), failure of recipient graft (4), reduction of physical abilities (1), high blood pressure (1), pneumonia (1) and infection of the urinary tract (1).<sup>49</sup>

In one of the Norwegian interviews the recipient, with the agreement of the donor, made a comment that might apply to many centres that the information had improved over time

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<sup>43</sup>1 and 2.

<sup>44</sup>1. The generally satisfied view of information provision seemingly correlates with positive comments made by most participants about the quality of care with comments including "very happy," "a good experience," "felt safe and in good hands," "felt secure," "trusted the professionals." One of the pairs who had expressed a reservation about the quality of information also said that donors should have more check up's afterwards (interview 2) although donor 1 who was satisfied with the information nevertheless stated that the hospital was disorganised in finding him a bed after the operation (interview 4).

<sup>45</sup>1, 4, 6, 7, 9, 10, 11, 13.

<sup>46</sup>15 and 16.

<sup>47</sup>21 and 22.

<sup>48</sup>In interview 1 the donor said the information was "good enough..though perhaps not as much as today." In interview 2 the doctors told the donor that there can be problems and put this in percentages. In interview 3 the donor states that there were meetings where there were so many people to talk to about the process. In interview 4 the donor and recipient simply said the information was 'great.' In interview 5 the donor commented that the information was very good but given what her sister was going through, "of course I was going to do this...I didn't really need information."

<sup>49</sup>1 donor did not remember what risks he was informed of, another donor stated he was only informed of the positive consequences (this was a twin donation).



having been "satisfactory most of the time" but "radically improved from 1989 (onwards)." <sup>50</sup>

### Informational Dependence

Donors in Slovenia, Poland and Slovakia were asked about their sources of information about LDT. Several of the 24 Slovenian donors received information about the positive and negative consequences of donation from more than one source. The main source was a nephrologist (19 donors) with other sources including surgeon (2), nurse (3), transplant co-ordinator, boyfriend and family doctor (1 each). Most donors did not seek out their own source of information (17) although a few did (4) - citing medical professionals and medical publications as sources.

Polish donors were typically informed of the positive and negative consequences of donation by more than one person. transplant co-ordinators (13 out of 21), nephrologists (14 out of 21) being most relied on surgeons (5 out of 21) and nurses (1 out of 21) much less so. In addition 13 out of 21 donors sought out additional information from other sources including medical books (2), press (7), ex-donors (7), television (6) and G.P.'s 2. The Slovakian donors had been informed of the possible negative and positive consequences by a nephrologist in all cases and also by a surgeon in one case. They did not seek information from other sources. 2 out of 3 were informationally dependent on one person.

### Informedness

These interviews did nothing to dispel the image of non-reflective donor decision-making exhibited within other studies. 20 out of 24 Slovenian donors knew they wanted to donate right away and did not need to think it over, stating that they were not aware of the risks at the time of deciding to donate. Apparently, donors were not very concerned about risks - 18 of them stated that a main worry was whether the transplanted kidney would work while only 3 stated their own health / medical complications as a main worry. At the time of the interview nearly half the donors (11) could not remember what risks they were told about, which is somewhat disturbing even if an allowance for lapse of time is made. Certainly there may have been an unconscious attempt to avoid ambivalent

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<sup>50</sup>12.



feelings that a genuine consideration of risks might have led to in many instances - a point confirmed by the underassessment of the risk factor in LDT with 18 donors stating LDT carried "no risk whatsoever" (4 answered "little or no risk" and 1 answered "a very small risk"). Polish responses were a little less extreme but even so a majority of donors still decided right away and nearly half were not aware of the potential risks at the time of donating.<sup>51</sup> Of the remaining samples only 3 Slovakian donors were interviewed<sup>52</sup> and none were interviewed in Romania.<sup>53</sup> However, some interesting qualitative points arose from the interviews in Leicester and Oslo. Whilst only one Leicester donor expressly stated<sup>54</sup> she decided before being aware of the risks<sup>55</sup> another, according to the recipient, refused to accept information beyond a certain point because "it'll put me off - if it happens it happens, that's it."<sup>56</sup> His decision was fairly automatic to give to his daughter, with no apparent reflection or weighing up of the risks and benefits. One Oslo donor<sup>57</sup> stated that he was met by a doctor who was explaining the risks and benefits to him, but after 4 or 5 minutes he interrupted saying "oh no problem." He added that,

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<sup>51</sup> 13 out of 21 Polish donors stated that they knew right away that they were going to donate and did not need to think it over. The remaining 8 donors only decided after talking to medical staff (and in some instances after the completion of tests also). 20 out of 21 donors did not reconsider their original decision to donate. Asked if they were aware at the time of making the donation decision of any potential risks to their health 11 donors answered that they were aware and 10 that they were not aware. Of those who were aware 4 said they were aware of general surgical complications, 2 of post-operative complications from nephrectomy, 1 of effects on postdonation physical capacity and 5 of problems which might affect the remaining kidney.

<sup>52</sup> At the time of making the decision to donate, 2 out of 3 Slovakian donors stated that they were aware of the risks to their health (1 specifying potential loss of the other kidney). The other donor, through not being aware could be stated to have not given an informed consent. The donors all specified only "whether the transplanted kidney would work" when asked their main worries. They did not in any case choose "your own health / medical complications." This could be viewed as a natural consequence, putting the recipient as the ill person first, but it could also be the consequence of denial or minimisation of the risks by such donors. All 3 donors stated that they knew right away that they wanted to donate and did not need time to think it over. 1 donor felt that there was quite a risk to his health in donating but the other two clearly distorted, or didn't understand, the reality by marking "no risk whatsoever."

<sup>53</sup> Although some data was collected regarding recipient decision-making: The 5 recipients were asked if at the time of their decision they were aware of any potential risks to their health. 3 responded no and 2 responded yes specifying knowledge of the possibility of rejection. Clearly there are some risks involved in transplantation for the recipient and this lack of knowledge in 3 out of 5 recipients is disturbing. Asked if they were aware of risks to the donor at the time of donation 1 responded no and 3 responded yes of which 2 specified surgical risks. 4 accepted the LDT only after talking to the donor and one accepted straight away not needing time to think it over. Respondents were asked what was *their* impression of the risk to their health. 2 marked the response "a very small risk" and two marked "quite a risk." They were also asked what they thought the risk was for the donor. 1 marked "little or no risk" and 3 marked "a very small risk." Perhaps the most interesting fact is that 1 recipient thought there was no risk whatsoever which is clearly not the reality.

<sup>54</sup> 4 and 5.

<sup>55</sup> She didn't have any regrets after the operation.

<sup>56</sup> 14.

<sup>57</sup> 2.



"I really didn't hear... I didn't want to speak about it because it was decided. (i.e. he had already made up his mind)."<sup>58</sup> One donor specifically commented that she didn't like hospitals and didn't want details of what was involved in the process.<sup>59</sup>

On the other side of the equation, one Leicester donor commented that he had two long interviews before deciding to donate.<sup>60</sup> The Oslo donors were perhaps the most informed in all the samples - some described risks of donation in great detail. For instance, one donor said "I knew I might have pain afterwards, that I might feel sick, .. about the possibility of narcosis"<sup>61</sup> another commented on the risks being well explained and added that he knew the success rate of living donation to be around 90-92% because of good statistics given to him and that he knew the wait for a cadaver kidney was one year or more with possible deterioration on dialysis.<sup>62</sup>

### **9.3.2.2. The Recipient**

#### **Disclosure**

Polish recipients were typically informed of more than one of the risks and benefits of LDT<sup>63</sup> (although 2 recipients reported that they were not informed of the positive and negative consequences) as were Slovenian recipients who were most commonly told of effects on the donors health (10), earlier transplant (10), pre-planned operation (8) and better match (12). From a selection of better match, pre-planned operation, earlier transplant, effect on donor's health and any other comments all 5 Romanian recipients only marked 'better match' in response to the question; "what risks/benefits were you told about?" Poland recipients had almost universally first heard about the possibility of LDT from medical staff, although 2 had found out from medical literature and 3 from a member of family / friend risks when they donated.

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<sup>58</sup>However, this donor was married to the recipient and had known for some time about her problems of kidney disease. It is therefore probable that he already knew at least some of the factors involved in donation.

<sup>59</sup>9.

<sup>60</sup>21 and 22.

<sup>61</sup>5.

<sup>62</sup>10.

<sup>63</sup>11 recipients mentioned being informed of better match, 9 of pre-planned operation, 11 of earlier transplant, 10 of the effect on the donor's health, 1 of the positive consequences of not being on dialysis. 1 recipient was not informed of any risks or benefits of LDT.



What these quantitative results do not convey is the mixed picture, as regards satisfaction with disclosure of interviewed recipients. 6 out of 10 Leicester recipients interviewed expressed concerns about disclosure as did a few of the Norwegian recipients.<sup>64</sup> Comments by Leicester recipients included: feeling "left in the dark... there was no real information" and that there was a lack of communication about what was going to happen in the operation. Specifically he was also not informed of a possible deleterious impact on his sex life from the operation, he also felt that his brother the donor (who could not be interviewed) had been treated like "a piece of meat;"<sup>65</sup> feeling uninformed about the possibility that her eyesight would deteriorate after the operation (she was diabetic);<sup>66</sup> feeling the doctors seemed to have no time "...I'm one of those people who likes to ask questions, it was frustrating. There was only one doctor who didn't talk down to you. They don't explain - sometimes you are left in the dark;"<sup>67</sup> feeling uninformed about drug side effects (including moon face);<sup>68</sup> and (a recipients wife)<sup>69</sup> feeling the recipient was not aware of many risks at the time of the operation, which had he been aware of them he might not have gone through with the operation.<sup>70</sup> One Oslo recipient felt that she could have been informed more about the medicines she would have to take and their side effects<sup>71</sup> and another felt that "sometimes the doctors forgot they were dealing with people."<sup>72</sup>

There were variations in who disclosed information and the degree of informational reliance of the recipient. In all 5 Romanian interviews instances a transplant coordinator had discussed with the recipients the positive and negative consequences of donation only 1 out of 5 had sought information from another source (being the medical literature). Polish recipients were also typically informed of the positive and negative consequences of donation by one person, this normally being the nephrologist.<sup>73</sup> Only 4

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<sup>64</sup>The recipient in Dublin interview 2 said going out into society was hard and she would have liked to have had counselling. This has now been introduced for donors, recipients and families of those with organ disease at the Dublin centre. An information worker is also available. Comments about the quality of care were positive except in so far as the recipient in interview 1 said the care was not as personal as it used to be and associated this change partly with the change to a bigger hospital.

<sup>65</sup>3.

<sup>66</sup>12 and 13.

<sup>67</sup>17 and 18.

<sup>68</sup>14.

<sup>69</sup>15 and 16.

<sup>70</sup>In this case the graft had failed.

<sup>71</sup>5.

<sup>72</sup>9.

<sup>73</sup>In 13 cases; a surgeon informed in 2 cases, nursing staff 1, psychologist 3, transplant coordinator 1, ex-patients 1, doctor in the USA 1, parents 1, ex-patients 1.



recipients had found information from sources other than medical staff although in mitigation it needs to be added that 5 of the recipients were minors at the time of receiving an organ; cases involving minors may have warranted a different approach. In Slovenia the positive and negative consequences of donation were primarily discussed by nephrologists (16), but sometimes by transplant co-ordinators (2) and nurses (5). In one instance these were stated as not discussed. A significant proportion of recipients (6 out of 22) sought information from other sources, primarily previous transplanted patients (2) and medical literature (2). All 3 Slovakian recipients had the positive and negative consequences of donation discussed with them by a nephrologist (being dependent informationally on this sole source),

### Informedness

6 Polish recipients knew right away and did not need to think it over;<sup>74</sup> 6 recipients reconsidered their original decision (of these 3 were worried for the donor's health and 2 others commented that they were thinking about / expecting a cadaver).<sup>75</sup> Amongst the 22 Slovenian recipients 12 recipients did not need to think over the decision to receive a kidney, deciding right away. The remainder talked it over with the donor and/or medical staff first. None of the 3 Slovakian recipients made immediate decisions to accept a living donor kidney - 1 talked it over with the donor first, another with medical staff and a third after talking with staff and the completion of tests.

Asked if they were aware, at the time of making the donation decision, of any potential risks to their health 12 Polish recipients said they were aware of risks to themselves and 10 said they were not aware. 14 recipients said they were aware of risks to the donor<sup>76</sup> and 9 said they were not aware. 2 out of 3 Slovakian recipients were not aware of potential risks to their health at the time of donation. 2 out of 3 were aware of potential risks to the donor, 1 of them citing the possibility that the donor might need dialysis in the future. 2 out of 3 Slovakian recipients felt aware of risks and benefits of LDT, citing 'better match.' All 3 felt there was "a very small risk" attached to being an LDT recipient while 2 assessed the risk to the donor as "a very small risk" and one as "quite a risk."

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<sup>74</sup>7 talked to the donor first, 3 were minors so did not make the decision themselves, 2 talked to staff and completed medical tests first and 3 talked to medical staff and the donor.

<sup>75</sup>13 recipients did not reconsider their original decision.

<sup>76</sup>Risks to the donor recipients focused on were loss of remaining kidney (9 recipients) and problems relating to surgery (3 recipients).



Only 8 out of 22 Slovenian recipients were aware of the potential risks of receiving an LDT when they accepted it. Those aware of risks all cited the possibility of failure of the transplant with one also noting the possibility of death. Most (17) were aware of risks to the donor at the time of acceptance most commonly citing the possibility of failure of the remaining kidney (5) and problems with it (7). Some recipients gave a number of responses when asked their main worries about receiving a kidney with the most commonly marked being the health and medical consequences for the donor (16) and whether the transplanted kidney would work (12). Some recipients were unable to accept the reality of risk - 9 personal assessing that there was no risk to their own health (6 little or no risk, 4 a very small risk and 3 a big risk). This also applies to some degree in respect of recipient assessment of the donor's position; 5 recipients stating that there was no risk (4 little or no risk, 4 a very small risk, 5 quite a big risk and 4 a big risk). Recipients were however on the whole much more realistic about risks to the donor.

Not much data was produced from the Oslo and Leicester samples on this question although one Oslo recipient commented that she may have shut some information out,

"well basically I was very ill... so I was not - I was restricting what I wanted to use my brains to cope with and somehow I did not er... want to study the risks or anything or ask questions about that because I just didn't want to know... this seemed to be the solution."<sup>77</sup>

#### **9.3.2.3. Conclusions**

A significant minority of donors expressly stated concerns about the quality of information giving and communication (sometimes recipients had concerns on the donors behalf as well). These were very serious concerns in some cases, particularly amongst the Leicester sample, however, in general concerns were higher with the recipients.

Time lapse led to significant recall problems but even given this there must be concerns about the level of informedness of donors:

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<sup>77</sup>13.



- *Firstly*, donors tended not to be able significantly detail what was disclosed and tended to tick only one heading when choosing from a list of the types of risks to choose from as factors that they were told about<sup>78</sup>
- *Secondly*, a small minority of donors stated that they had not been told of any risks.
- *Thirdly*, they tended to rely on one source of information; *and*
- *Fourthly*, most donors made an immediate decision to donate without thinking it over or talking to medical staff.

Donors also tended to underestimate the significance of risks, which combined with the above factors suggests that many of them were unconsciously attempting to avoid feelings of discomfort relating to the decision to donate.

Recipients tended to have a slightly higher ability to describe risk and benefits of donation and more awareness at the time of deciding to donate. They also had a less degree of informational dependence - tending both to have more sources of disclosure and communication than donors<sup>79</sup> and to seek out their own information more.

### **9.3.3. Voluntariness in LDT.**

Motivation in LDT, as evidenced for instance by pre and post donation feelings about is important both in its own right and for verifying or otherwise that the decision to donate or receive was made on a voluntary basis. Other areas of data pertinent to voluntariness are the situational context of donation (a potential indicator of motivation, pressures and influences), recognised pressures and attitudes towards different classes of donor. Most of the findings in these areas relate to the donor, although points are specified in relation to the recipient on occasion.

#### **9.3.3.1. Why LDT Was Chosen**

In the Slovenian sample the recipients stated in 17 out of 22 instances that there was more than one person offering to give them a kidney with the final decision almost always being stated as having been taken on medical grounds. The donors had a slightly different perception of the situation with 15 out of 24 saying someone else had also

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<sup>78</sup>As they were in Slovenia, Slovakia and Poland.

<sup>79</sup>But still only sometimes.



offered. The final decision was invariably grounded in medical reasons, but in 1 case it was classified as 'psychological' and in another the alternative donor was in a greater state of fear about the donation. No data was available on the choice of LDT in preference to cadaveric donation. In 2 out of 3 Slovakian cases donors they said they were the only person offering and were finally chosen for medical reasons which all 3 recipient said had been the basis for their decision. No data was available of preference for LDT over cadaveric. In Romania in 4 out of 5 instances there was only one person offering a kidney. This seems somewhat unusual since even if there was only one available close genetic relative, in 4 out of 5 cases the recipients were married and spousal donation might have been an extra option. In 4 instances the recipient stated that the particular donor was chosen for "medical reasons"<sup>80</sup>

In Leicester one recipient<sup>81</sup> had a failed cadaveric transplant and continued to resist living donation for a further 4 years before accepting. A large range of family members were tested for suitability as donors, the final choice being medically based. One donor<sup>82</sup> stated that, "it was a natural thing to do" and appeared mocking and laughed ironically about the recipients brother refusing to donate because of "something to do with insurance." "Oh well he's rather arrogant - he and his wife are hypochondriacs." A further donor<sup>83</sup> simply said he "basically thought that it was a good idea," whilst another donor<sup>84</sup> had not liked to see her brother ill and so had offered to donate. In another interview<sup>85</sup> it was clear that there were other living donor options but these were not considered. Asked why her mother was not considered the recipient simply stated that she "thinks her mother would not have been able to cope with being a donor." In one interview<sup>86</sup> the donor, whilst not regretting his decision to donate to his sister, appeared to be very angry that her husband had refused to consider donating - feeling this was very selfish. In two further cases<sup>87</sup> the decision to use living donation may have been heavily influenced by the fact that the recipients were minors in considerable distress on dialysis.

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<sup>80</sup>The 5th did not respond to this question.

<sup>81</sup>6 and 7.

<sup>82</sup>4 and 5.

<sup>83</sup>15 and 16.

<sup>84</sup>1 and 2.

<sup>85</sup>14.

<sup>86</sup>12 and 13.

<sup>87</sup>8 and 9, 10 and 11.



One recipient in the Oslo interviews had a genetic family whose members were precluded from donating by the nature of the kidney problem. His spouse donated because she "hoped to help my husband.. I had seen so much.. after I had seen his illness I wanted to do something." In a further Oslo interview<sup>88</sup> the donor said "it was not a nice feeling" that the recipient had two rejection crises and he felt very down "if that happened - to give a kidney and it should not succeed - I wouldn't like to think of that." This may suggest that altruism in the sense of a 'detached compassionate giving' was not fully present. The donor's feelings about the donation hinged partly on its outcome. It is uncertain whether or not he would regret his donation had it failed but this is possible. In a different interview the recipient had a part of the kidney taken out with the fear that that might be the end of the graft, but when I asked the donor if the failure of the graft might lead to feelings of rejection of what had been given, the donor responded "it was not because it was mine it was because it was my sister."<sup>89</sup> Participants in the Oslo interviews generally expressed views on living donation as compared with cadaveric donation. 7 pairs indicated a specific preference for LDT over cadaver.<sup>90</sup> Thoughts on this point included: The fact that cadaver donation had a long waiting list;<sup>91</sup> LDT offers the chance to prepare for the operation and be in control of timing more;<sup>92</sup> a lesser rate of rejection / better success rate;<sup>93</sup> LDT offers the chance for someone else to have a cadaver instead;<sup>94</sup> and one donor rather surprisingly said that he simply hadn't considered cadaver as a possible first option!<sup>95</sup>

Some participants in the Dublin interviews expressed views on the preference for living donors. In interviews 2 and 5 the quality of the match was mentioned, with the matches being very high at 95 and 100% respectively. In interviews 1, 2 and 5 the graft had survived a long time, perhaps indicating that this was anticipated when the decision was made to donate. In interview 1 the recipient was deteriorating in health rapidly and required 10 hours inclusive of travel time, each time he dialysed, thus a quickly arranged and executed transplant as afforded by living donation was very beneficial.

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<sup>88</sup>3.

<sup>89</sup>7.

<sup>90</sup>1, 8, 9, 10, 11, 12, 13

<sup>91</sup>1, 8, 11.

<sup>92</sup>8, 12.

<sup>93</sup>8, 9, 10, 12.

<sup>94</sup>11.

<sup>95</sup>13.



### **9.3.3.2. Feelings About the Decision to Donate or Receive.**

A few donors expressed ambivalence about their decision. In Slovenia 2 out of 24 cases the donor reconsidered the original decision, on one occasion this was because there had been a delay of a year after offering and a lack of information, on another occasion the donor was afraid for the recipient.<sup>96</sup> Asked if they would go through the process again if the 'clock was turned back' 2 Slovenian donors said no - the reason in one case being that the donor had "lost money in his job" and in the other that being that the donor had waited a long time for it to happen. 1 Polish donor also felt this way - he had not realised that the donated organ would not function for a lifetime. Similarly there were 3 recipients who would not go through the whole process again - one in Leicester who had had severe health problems and 2 in Slovenia, one of whom simply stated a preference for cadaveric donation while the other was concerned about graft failure (the reason for this latter concern was not expressed although it was clear that the recipient had had a number of failed grafts). There may be a connection here with the fact that 7 responding Slovenian recipients found the decision to donate extremely / very difficult.<sup>97</sup> A number of Polish recipients also found it hard to accept a kidney.<sup>98</sup> There was also some ambivalence at points in the decision-making process for a very small number of recipients including 2 out of 3 Slovakian recipients who had reconsidered their decision (but did not say why), as had 1 out of 22 Polish recipients (through being worried for the health of the donor). The recipient in one Leicester interview had uncertainties at various points after LDT partly connected with the fact that the graft had failed.<sup>99</sup>

However, the main picture was that donors and recipients were happy with their decision, regret was not a significant factor in any of the interviews in Leicester,<sup>100</sup> Dublin (where the 3 out of 5 donors reflecting on this were happy with their decision),<sup>101</sup> Romania<sup>102</sup> or Oslo.<sup>103</sup> Positive attitudes were most illuminated in Oslo and included: disappointment that the kidney had failed but feeling the right decision had still been made;<sup>104</sup> "I can

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<sup>96</sup>The reason for this fear was not stated.

<sup>97</sup>5 said it was quite difficult and 10 not very difficult / easy and 10 found it not very difficult / easy

<sup>98</sup>7 said it was extremely difficult, 3 very difficult and 1 quite difficult; 6 recipients found it easy or not difficult.

<sup>99</sup>15 and 16.

<sup>100</sup>4 and 5, 6 and 7, 8 and 9, 10 and 11, 17 and 18, 21 and 22.

<sup>101</sup>1, 5.

<sup>102</sup>None of the 5 recipients had ever reconsidered their decision to receive LDT.

<sup>103</sup>There were no negative comments expressed about living donation although it must be stated that this may have been influenced by donors having been picked by a nephrologist at the Oslo centre.

<sup>104</sup>1.



recommend it" seeing the recipient recover was "the best happening in my life..I never had such an experience in my life;"<sup>105</sup> it was a normal thing to do;<sup>106</sup> it was "very natural...I'm very satisfied;"<sup>107</sup> "a natural process;"<sup>108</sup> a donor feeling fear about the process but stating this was more on the surface with deeper feelings in favour of donation;<sup>109</sup> a further donor fearing hospitals but wanting to help out her sister.<sup>110</sup>

### 9.3.3.3. Unconscious Motivations

Besides the question of most decisions to donate being made instantaneously and risks being underestimated other issues having a bearing on unconsciousness of motivation arose. Of course these issues would only have a bearing on the legal position if they indicated incapacity or were combined with an external pressurising agent.<sup>111</sup>

One of the factors that could reduce the incidence of unconsciously motivated donation is the donor being offered the opportunity to change their mind without the family knowing the real reason. The donors given this opportunity included: 2 out of 24 in the Slovenian sample; 5 out of 21 in the Polish sample (plus 1 recipient); at least 2 out of 5 in the Dublin sample;<sup>112</sup> 3 out of 3 in the Slovakian sample (plus 2 recipients); and 1 out of 5 Romanian recipients.

Another relevant issue is whether recipients feel indebted to the donor and if so whether feelings of indebtedness in any way reduced the value of donation. Recipients were equally divided in the question of whether they were indebted to the donor and interestingly a significant minority experienced this as a burden (e.g. 3 out of 11 Oslo recipients, 4 out of 10 Polish recipients and 0 out of 3 Romanian recipients).

In the Leicester sample some interesting comments arose around this theme. In interview 1 and 2 the recipient expressed gratitude but did not have any sense that he had to pay the donor back in any way. The donor in interview 12 and 13 had been

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<sup>105</sup>3.

<sup>106</sup>2.

<sup>107</sup>8.

<sup>108</sup>11.

<sup>109</sup>7.

<sup>110</sup>9.

<sup>111</sup>See chapter 7 for further details of this debate.

<sup>112</sup>1, 5.



"showered with gifts" by his sister-recipient, to which he felt embarrassed since he "would have done it for anybody in the family." The recipient in interview 17 and 18 felt that he owed the donor "a great debt but I don't have to repay it."

Linked to the question of indebtedness is the issue of whether donation can ever be a free-gifting altruistic act. From a phenomenological point of view it is possible to distinguish decisions at one end of a spectrum which are made in accordance with a persons true will and reflect their core values, potentially including expressions of compassion through gifting and other activity, and the other end of the spectrum decisions which are superficially based on automatically assumed socialisation (of society and/or family etc.) and/or the product of other unconscious processes. A vivid example of this being grappled with occurred in the 13th Norwegian interview, an extract of which is presented in Figure 6 below.

**Figure 6: Is There a Reality to 'Free' Gifting?**

Donor: ...it was just a matter of course. That's how it is.

Me: Somehow then, er just sort of...the right thing to do

Donor: Oh yes...there's a problem that you have no other choice but er... you were very glad also that you were accepted as a donor (laughing).

Recipient to Me: ....But may I ask a question? Although you are doing the questioning!

Recipient to Donor: You say you had no choice and I think that I understand what I mean but isn't that sort of contrary to what the situation should be. I mean when, isn't it supposed to be that before people become living donors ...shouldn't he have a choice...I mean you felt compelled to do this - or what do you mean by 'had no choice'?

Donor: I think that first of all of course you have a responsibility as a father, you have to live up to that and you have to do the best for your own child...that's one thing and er.. if I had been asked and given the possibility to say yes or no I would feel like there's no question of yes or no in a situation like ours. this was, as I tried to put it, as a matter of course and on that point there was no question of a choice. We had never thought of doing anything.. I was I would say very blessed that I was able to do this sort of thing. It generated great happiness. One could say beforehand that we should do it together, we should fix it, and then the situation was clear, there were no obstacles, it was go ahead.

Me (later): ...when you say you have no choice that can be taken in two ways and I take it one way but some people would say they have no choice and this meant they were like forced or pressured.

Donor: Yes but I didn't mean it that way.

Me: Yes, like this was a different kind of feeling of no choice..you know that this was just the right thing.

Donor: Yes at this stage it (the choice) did not exist and that way I was not given the choice in a positive way.

Me: Umm (listening).

Recipient: I have been thinking a bit about that - both my parents have a terrible sense of duty - you know a sense of duty to life in general.. and er er.. I saw that particularly right before we had the surgery... and you know I knew that things could go wrong and I thought that would be absolutely awful - I couldn't live with that but then I sort of remembered the situation at the summerhouse. I was sitting on the terrace over breakfast and I sort of put this question sort of timidly and I just remembered they both jumped in their chairs and said, 'please I want to do this.' This spontaneous reaction was my proof that this was really something they wanted to do and not something they felt they should do from any kind of negative duty..so I sort of cling to that (laughing). That was very important to me.



In interview 9 of the Oslo interviews the participants reflected upon the possibility that illness in one person can result in them adopting an "ill role" with other members of the family taking on the supporter role focusing their attention on the ill person. This could indicate a psychological patterning relating to these 'roles' with one person 'needing to be saved' while the other 'needs to save.'<sup>113</sup>

#### **9.3.3.4. Proactive or Reactive Approach in LDT**

In the main the study found that patients are pro-actively *informed* of the possibility of LDT as distinct from doctors only discussing it in response to a patient enquiry. Half the 24 Slovenian donors half had first been told by the recipient that (s)he needed a transplant. Most of the others had been first been told by other medical staff, although one person had found out through a medical publication and another by television. In the Polish sample in 17 cases someone explicitly made the donor aware that the recipient needed a transplant; a member of the medical staff in 14 cases,<sup>114</sup> the recipient himself / herself in 2 cases and in one case the sister-in-law. This hints at a certain degree of medical staff proactivity in informing prospective donors but whether a proactive approach to LDT is routinely taken is uncertain, especially given that about half of the recipients first heard of the possibility of LDT from a non-medical staff source (e.g. family member in 6 cases, ex-patient in 3 cases). In Slovakia of the 3 donors responding, 1 had first become aware that the recipient needed a transplant from the recipient, the other two from medical staff.

Of 22 Slovenian recipients nearly half (10) had been informed of the possibility of LDT by a kidney specialist, most of the remainder had heard from other medical staff but in 2 instances a patient had found out through the literature and in a further 3 cases from a member of family / friend. Of the 3 Slovakian recipient respondents 2 explained that

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<sup>113</sup>The interview reflected this with the focus being heavily on the recipient. Despite several invitations on my part, the donor did not speak much. The underlying feelings may respectively involve manipulation / attention seeking and guilt / compulsive need to feel useful.

<sup>114</sup>In the case of medical staff this was frequently a nephrologist or member of staff in the dialysis unit.



they had first heard it was possible to have a kidney from both a kidney specialist and another patient.

A significant minority were actually *asked* to donate as opposed to simply being *informed* the donor needed a kidney. Half the Slovenian donors (12 of 24) had been asked to consider donating their kidney on 6 occasions by the recipient, 4 the nephrologist, once both and once unstated. 10 donors agreed explicitly that they donated without being asked. In Slovakia 1 of the recipients stated that (s)he had asked the donor to donate and another said that a nephrologist had asked. In Romania 3 of the 5 recipients had asked someone to give them a kidney. In all instances the mother was asked. In the Leicester interviews one recipient<sup>115</sup> had tentatively, and in an embarrassed way, asked his brother. In Poland 4 cases out of 21 recipients specifically asked someone to donate. In 7 of the cases where they did not ask, someone else did. These figures approximately correspond with the perceptions of the donors.

#### 9.3.3.5. Direct Pressures

None of the donors in any of the sample stated that they were pressured to donate or otherwise intimated this. However, 5 out of 21 donors in the Slovenian sample *experienced pressure not to donate*.

A small minority of recipients felt pressure to receive including 1 out of 22 in the Slovenian sample (pressure from the donor), 1 out of 3 in the Slovakian sample (by the donor and by parents) and 3 out of 23 in the Polish sample (specifying pressure by medical staff in 1 case and by medical staff in two others). In one Norwegian interview the question of possible pressure from doctors was unanswered with the recipient stating that it was the "doctor's decision" based on the "hurry to get a kidney." There is no evidence there was any particular hurry in this instance, so it could be that the doctors were not neutral in their discussions.<sup>116</sup>

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<sup>115</sup>3.

<sup>116</sup>One could hypothesise that they were partly influenced by the utilitarian consideration that another living donor would free up the waiting list a little. It is possible, however, that the recipient was using her words casually and inaccurately.



1 Slovenian recipient felt pressure *not* to accept (coming from members of the donor and recipient families). 2 out of 21 cases Polish recipients stated that medical staff had tried to persuade them and in 1 case out of 18 LDT had caused family pressure.<sup>117</sup>

On the other hand there was some evidence of donation on the whole not being pressure. None of the Slovakian donors or recipients or the Romanian recipients felt the medical staff had tried to persuade them in one way or another although. In Dublin in interviews 1 and 2 the donor specifically stated they did not feel any pressure to donate or otherwise. There are also some good qualitative examples in the Oslo sample of donation appearing not to be based on pressure: One donor stated that she "did not feel any pressure to be a donor, completely voluntary.. no threat of pressure from the hospital - my own decision." Further evidence that she had chosen out of her own will comes from the fact that the kidney had been rejected and yet she "still did not regret anything..but of course it would be much better if he could have kept it." A further donor (interview 3) had married the recipient knowing that she had kidney problems which might get worse. However in the interview this was clearly a sign that he knew what he was getting into rather than a sign of possible dubious (e.g. commercial) motivation for marrying her. In one instance a man had donated to his brother in law (who had the same rare blood group type), there being no evidence of dubious motivation in this case.

#### 9.3.3.6. Conclusion

Donors generally expressed positive feelings about the donation with negative feelings confined to specific aspects of the process<sup>118</sup> rather than relating to the fact of having donated. There was no evidence of psychopathology in donation and only 3 donors and 3 recipients who experience post donation regret. In addition none of the donors expressed the view that they were pressured to donate.

Whilst these are significant findings, the potential for unconscious motivations is high and just as donors often deny the reality of risks it is possible that they will deny the presence of pressure or, where it is more subtle or situational, not even be aware of it.

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<sup>117</sup>The reason given being that the donor was found to have a psychological disorder (post-transplant)

<sup>118</sup>E.g. quality of information disclosure.



Over the centres as a whole there is clearly a mixture of ways being utilised to bring about living donation. Typically donors are informed of the recipients need, then in many instances left to take the initiative and in others actually asked, usually by the recipient or medical staff. A proactive approach to *informing* potential donors can meet little objection the question is whether actually *asking* is acceptable given that it probably amplifies the situational pressure that may be experienced by donors - i.e. making it harder for them to refuse. Clearly if prospective donors are to be asked it is preferable that this is done in a way that minimises pressure e.g. by a member of the staff not involved in the care of the prospective recipient and is expressly giving the prospective donor a way out without losing face - at this stage this is not routinely done in the centres sampled except for Oslo.

### **9.3.6. Attitudes Toward Different Classes of Living Donation.**

In Poland donors expressed their views about different forms of living donation being totally in favour of closely related donations (19 out of 19) and very solidly in favour of spousal (14 in favour, 3 against and 2 not sure), distantly related (17 in favour and 2 not sure), friends (15 in favour and 4 not sure) and strangers (16 in favour, 1 against and 2 not sure). A similar picture in favour of donation was presented with recipients being in favour of closely related donation (18 in favour, 1 against and 4 not sure) although there was more ambivalence with other classes of donation (spousal donation 13 in favour, 4 against and 6 not sure; distantly related 16 in favour, 2 against and 5 not sure; friends 13 in favour, 6 against and 4 not sure; and strangers 13 in favour, 3 against and 7 not sure).

In Slovakia recipients were unanimously in favour of all classes of donation except between strangers; which 2 out of 3 recipients were in favour of. Donors were in favour of close and distant related donation but mixed in response to spousal and friends (1 in favour, 1 unsure, 1 against) and strangers (1 unsure, 1 against).

In Slovenia donor views expressed on different forms of living donation were totally in favour of closely related, largely in favour of distantly related (22 in favour, 2 unsure) and spousal (21 in favour, 3 unsure) becoming slightly more ambivalent for friends (18 in favour, 2 not and 3 unsure) and strangers (15 in favour, 4 not and 6 unsure). The recipient picture of attitudes toward living donation generally was that 22 of 22 were in favour of closely related while in all other forms there was ambivalence but still a general picture of favourability.



In Romania recipients expressed their views about different forms of living donation, being in favour of closely related donation (4 out of 4), against distantly related, friends and strangers (5 out of 5) and uncertain about spousal donation (5 out of 5). 3 out of 4 recipients felt they would go through the process of living donation again. The recipient who would not have gone through it again did not state why.

In Albania attitudes toward transplantation were generally favourable amongst relatives of renal patients but interestingly almost 1 in 5 people with a definite view about cadaveric donation were against it. LDT by close relatives was fairly unequivocally favoured (96%) and even spousal donation was marginally preferred to cadaveric (78% for spousal; 71% for cadaveric). Positive attitudes toward LDT do not typically apply to donation by friends and strangers (61% and 78% against respectively) although a minority was in favour (22% and 12% respectively).

To conclude, attitudes towards different forms of donation were: Almost exclusively in favour of closely related donation; very much in favour of distantly related donation; largely in favour of spousal donation (several Oslo interviewees from their personal experience recommended the use of spouses as living donors with one couple<sup>119</sup> suggesting that it was a better alternative than offspring); and, to a lesser extent, in favour of donation by friends. However, attitudes were fairly equally divided and ambivalent about strangers as donors. Perhaps the most interesting point about these findings is that participants have a much more liberal attitude than professionals to classes of potential living donors.<sup>120</sup> To some degree this was expected; those going through the process tend to focus on the benefits and the need for more transplants, professionals also do this but they probably also focus much more on the ethics involved with different classes of donor, the potential dangers (e.g. commercialisation, psychopathology) and the need to 'be seen' to do something that most of society will accept.

The attitudes of Albanian families are worth a particular mention: they are sufficiently in favour of living donation to suggest this might be a vital source of organs when Albania commences a transplant programme. 16% of respondents were against cadaveric donation; a figure that is of some concern because it is likely to be amplified in the

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<sup>119</sup>12.

<sup>120</sup>See chapter 9.



general population and would present resistance to a cadaveric programme. Religious attitudes (predominantly Muslim, Catholic and Orthodox) may prove to be a particular barrier.

### **9.3.7. Issues Relating to Capacity.**

Data here was limited to one interview with a minor donor-recipient pair in Dublin who were identical twin sisters who nearly 14 years old at the time of donation. The doctors had made it clear to the donor that she could change her mind at any time. She said, "that thought never occurred to me." She added that "I knew I'd have the best match..I couldn't really understand the commotion of it...the doctors explained to me what it would all involve but when I heard..it didn't matter what was involved. With what she was going through of course I was going to do this." The donor said the information "was very good" but felt she really didn't need information (i.e. already knew her decision). The recipient adds that "there was a lot of information." The donor said she would have been more aware of the side effects if she had been older.

It is difficult to be sure from the interview whether informed consent was given by the donor. Largely the process for the donor seemed to work along the same line as some adults who make the decision without any lengthy reflection on details about risks etc. More evidence would be valuable in this area but difficult to find because of the rare incidence of minor organ donation.

### **9.3.8. Financial Aspects of Donating and Receiving.**

#### **9.3.8.1. Buying and Selling Organs**

While there was no evidence of buying and selling some information was collected about attitudes towards it. Of the 21 Polish donors, 13 were against the buying and selling of organs, 2 were in favour of it and 6 were unsure. Of the 23 recipients, 12 were against the buying and selling of organs, 3 were in favour of it and 8 were unsure. In Slovenia there was some ambivalence about buying and selling of organs amongst donors (8 not in favour, 6 not sure and 2 in favour) although a remarkable 19 of 22 would have considered buying an organ for the recipient. Slovenian recipients were almost universally against the buying and selling of organs (19 against, 1 in favour 2, not sure)



but were far more ambivalent about considering buying an organ for an actual sick relative (7 would have considered, 15 wouldn't).

In the Leicester sample complete disagreement with the buying and selling of organs was expressed by 6 participants.<sup>121</sup> One participant in favour<sup>122</sup> stated that there was nothing wrong with commerce; "somebody gets paid and saves someone else's life." Two further participants made very qualified statements: The donor in interview 12 and 13 basically didn't agree with the buying and selling of organs but added that "everybody has their price and it depends on your situation;" the donor in interview 21 and 22 felt it was alright if the recipient wanted to reward the donor in some way. In Albania 90% of responding family members of ESRF patients were against the buying and selling of organs. 10% were in favour. 4 out of 5 Romanian recipients were against the buying and selling of organs and would not have considered it, one was in favour and would have considered it. Slovakian donors were all against the buying and selling of organs but 2 out of 3 would have bought one for their relative. Contrastingly, the recipients were all against buying and selling and none would have considered buying an organ for a sick relative.

#### 9.3.8.2. Compensation for Loss

In Slovenia average time after donation before returning to work / normal everyday activities was approximately 2 and a quarter months, with variations from 2 weeks to 9 months. 13 donors had received time off work on full wages, 1 on 85%, 2 just time off and 3 did not get time off. In one instance the job was not kept open for the donor. 3 said they were able to claim state benefit of social and health insurance at 100% of their earnings level, 20 said they couldn't get state benefit but most of these appear to have got full wages anyway. Asked if donating the kidney had affected them at all financially 19 donors said not at all, 3 a little and 2 a great deal. 2 of these respondents incurred a 30% income loss and one felt it had affected him positively to a great extent. None of them got compensation from the recipient.

In the Leicester sample the recipient in interview 3 lost £2000 paying the donor's travel expenses and lost salary which "really broke" the family finances. He would have liked

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<sup>121</sup>Recipients in 1 and 2, 4 and 5, 8 and 9, 14, donor and recipient in interview 19 and 20.

<sup>122</sup>Donor in 4 and 5.



more support from the hospital. The recipient in interview 6 and 7 was initially put off living donation for a number of years because help with expenses was not available. The recipient in interview 15 and 16 said that it had been difficult for his family financially. The donor in interview 21 and 22 suffered some financial hardship, which had been partly alleviated by the recipient.

In the first Oslo interview the donor stated that social security did not cover all of her expenses. The opposite was the case in interview 6. In interview 8 the participants stated that the donation caused no financial hardship. In interview 10 the donor expressed the view that transplantation saved a lot of money and could be encouraged by fully compensating donors for travel expenses and loss of earnings.

One donor in the Dublin interviews had been economically disadvantaged by the fact that taxi and bus fares to and from the hospital could not be claimed. The recipients in the Romanian interviews assessed that donation had affected the donor financially "a great deal" in one instance, "a little" in 2 cases and "not at all" in the remaining 2. 1 donor was perceived as having received compensation for losses in connection with the donation with 4 not being compensated.

Of the 3 Slovakian donors there were no reported adverse effects on their employment. 1 donor was able to return to normal everyday activities after a month, the other 2 did not answer this question. 2 out of 2 donors got time off work from their employers, all 3 were partially compensated for lost earnings through sick pay. Despite this, and one person marking that they had travel costs, all of them marked that donation had not affected them at all financially. The recipients confirmed this.

### Future Economic Impact

In some interviews comments were made about the economic impact of LDT in terms of subsequent employment. Of the 3 Slovakian donors there were no reported adverse effects on their employment. In Slovenia 2 out of 24 donors felt donation had affected their performance at work, these being fairly mild deleterious effects. 3 donors reported an adverse impact on income, 1 an improvement and 19 no impact. 2 felt it had affected promotion, in a positive way.



13 out of 22 Slovenian recipients felt that donation had affected their performance at work, 8 in an adverse way and 5 in a positive way. 7 out of 22 felt it had affected their income; 4 in a positive way and 3 in a negative way. 3 out of 21 felt it had affected promotion, all in a positive way. It took recipients between 1 month and 2 years to return to work / normal everyday activities. The average was 6 months, which is quite a long time and may have significant ramifications in terms of potential financial hardship although in fact 21 of 22 recipients felt that the transplant had not affected them at all financially (it had affected 1 a great deal). 1 out of 22 had received compensation for losses associated with the donation, this being from a health insurance company. In Romania of 5 recipients, 2 felt that receiving a kidney had improved their performance at work, no adverse effects were reported in this regard.

The donors were not systematically asked about the impact of donation on their ability to obtain life insurance. However, in Dublin one donor had difficulties in obtaining life insurance. In Slovenia only 1 donor had applied for life insurance and had not had any difficulty.

#### Attitudes Towards Compensation for Loss.

Attitudes towards compensation for losses were mixed. Of 21 donors and 18 recipients expressing a view on this in Poland, 9 donors and 5 recipients were in favour of such compensation, 10 donors and 11 recipients were against it. 2 donors and 2 recipients were not sure. Slovenian recipients were more equally divided over the question of whether any payment should be permitted such as compensation of losses (12 no, 10 yes) with comments including; a health insurance company should compensate, moderate award should be given and donation should be a non-commercial voluntary / emotional act. Slovenian donors were also roughly equally divided on this question (10 yes, 11 no, 3 not sure). Comments in favour of compensation included suggestions for health insurance company compensation and compensation for lost earnings. The majority of Romanian recipients felt compensation was acceptable (4 out of 5 - this was not surprising given 3 out of 5 donors had suffered financially from donation). The Slovakian donors all responded "no" when asked "should any payment be permitted, for example to compensate for losses incurred." All but one recipient responded no this question.



### **9.3.8.3. Conclusions.**

The impact of donating an organ on employment status appears to be limited. Occasionally material adverse effects are observable in terms of performance and income. In a significant minority of 19 cases moderate to severe financial consequences of donation were reported. This was not surprising since it was clear that there tended not to be full compensation for donor losses. It was explicitly stated in 2 cases that the recipient had helped the donor out in terms of expenses associated with donation. One of the recipients reported that having to pay the donors expenses had contributed greatly to stress within the family. Little data was available on the consequences of donation for life insurance.

Where attitudes towards commercialisation of organs were expressed by donors and recipients the general consensus was against the practice (68 out of 103) but there was a sizeable minority who were uncertain or had mixed feelings (24) with the remainder in favour (11). However, asked if they would consider buying a kidney for a relative a remarkable 32 from 55 respondents said they would. The attitudes amongst ESRF patient family members in the Albania sample were generally against the buying and selling of organs.

## **9.4. Overall Conclusions for Donor and Recipient Questionnaires.**

The first thing to note about the study is that limited interviewee recall exerted a distorting influence on the findings. In particular limited recall makes it difficult to determine quality of practitioner disclosure. Nevertheless, the research brings out some important issues and findings.

In a limited way the findings resonate with the bulk of earlier work which suggests adverse psychological aspects of the process of donation are extremely limited.<sup>123</sup> There were 3 out of 84 incidences where recipients would not go through the process again. There were 3 out of 76 donors who would not go through the process again - this 4.5% representing a slightly lower figure than the 5% - 8% reported in R.G.Simmons et al.'s

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<sup>123</sup>See chapter 3.4.2.3.



sty<sup>124</sup> and significantly higher than the 1.4% in Westlie et al.'s study saying they definitely would not donate.<sup>125</sup>

This study also confirmed the broad notion in several earlier studies that donation can result in increased self-esteem for some donors.<sup>126</sup> However, the increases were fairly low compared to some previous studies. For instance, a number of studies conducted by Simmons et al. found that donation was typically an exceedingly positive experience.<sup>127</sup> Studies by Fellner and Marshall,<sup>128</sup> Eisendrath,<sup>129</sup> Bunzendahl et al.,<sup>130</sup> and Westlie et al,<sup>131</sup> have also reported higher levels of positive impact.

This study found little family stress and strain - although one might have found slightly higher incidence of problems if the methodology had been more family oriented and the interviews conducted at the time of donation rather than at a later date when stress and strain might be 'played down' to avoid discomfort.

Whilst previous studies found pressure to donate in a significant minority of incidences this study found no cases. However, pressure by its nature is difficult to detect, especially when it is subtle or systemically embedded. In addition, one must be cautious about ascribing altruistic motivation to donation when the reality is that few donors can clearly articulate their rationale for donation. Many donors appear to have decided without any real reflection on the issues - an approach already seen in landmark

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<sup>124</sup>The Gift of Life: The Social and Psychological Impact of Organ Transplantation, *John Wiley & Sons*, 1977 at 431-3.

<sup>125</sup>L. Westlie et al., Quality of life in Norwegian Kidney Donors, *Nephrol Dial Transplant*, 1993, 8, 1146-1150.

<sup>126</sup>See chapter 3.4.2.3.

<sup>127</sup>R.G. Simmons, S.D. Klein, R.L. Simmons, The Gift of Life: The Social and Psychological Impact of Organ Transplantation, *John Wiley & Sons*, 1977 confirmed in a later follow up (R.G. Simmons, C.R. Anderson, Social-Psychological Problems in Living Donor Transplantation, in J.L. Touraine et al., (ed), Transplantation and Clinical Immunology XVI, *Elsevier Science Publishers*, 1983, 47-57).

<sup>128</sup>C.H. Fellner, J.R. Marshall, Twelve Kidney Donors, *J. Am. Med. Assoc*, 1968, 206, 2703-2707 and Kidney Donors Revisited, *Am J Psychiatry*, 1977, 134, 575-576.

<sup>129</sup>R.M. Eisendrath, Psychologic Considerations in the Selection of Kidney Transplant Donors, *Surg Gynec Obstet*, 1969, 129, 243-248. See also, The Role of Grief and Fear in The Death of Kidney Transplant Patients, *Am J Psychiatry*, 1969, 126, 381.

<sup>130</sup>Retrospective Evaluation of Psychosocial Factors in Former Living Related Kidney Donors in Organ Replacement Therapy: Ethics, Justice and Commerce, (ed. Land and Dossetor, *Springer Verlag*, 1991 at p57). Similarly improvements in self esteem had been found in Sadler et al's study (in The Gift of Life: The Social and Psychological Impact of Organ Transplantation, *John Wiley & Sons*, 1977, p502).

<sup>131</sup>Quality of life in Norwegian Kidney Donors, *Nephrol Dial Transplant*, 1993, 8, 1146-1150.



studies by Fellner and Marshall<sup>132</sup> and Simmons et al.<sup>133</sup> While it is difficult to be certain, underestimation of risks in this study may be connected with Fellner and Marshall's finding that donor's insulate themselves from cognising information that would result in decision stress by challenging their decision (in this case to donate but it could also be relevant to the decision not to donate). Certainly underestimation of risks and forgetting about the risks do support the goal of avoiding ambivalence about donation and discomfort with its realities.

Fellner and Marshall's asserted that some donors "go along passively and let the selection process decide for them"<sup>134</sup> and Simmons et al.'s assertion that some donors exhibit helplessness in the form of feeling locked into making a positive decision, more so with each successive step of the donation process.<sup>135</sup> This finding was neither supported or contradicted in the interviews.

The one thing that may be stated in defence of donors in the modern age is that the benefits of LDT are often much higher than they were at the time of Fellner and Marshall's (1968) or even Simmons et al's (1977) report; this points toward it being easier for donors to quickly conclude that donation has value. On the other hand, CDT is now so well established that an immediate unreflective decision to become a living donor could quite typically be viewed as an overly hasty rejection of CDT - perhaps often motivated more by a 'saviour complex' than by common sense. The vulnerability of donors, and even recipients, to making decisions out of guilt or for other negative reasons and then suppressing the reality of this are amplified by their typically being dependent on one source of information for LDT. A model protocol for living donation could valuably be developed to include best practice directions for minimising situational pressure in all its dimensions within the prelude and process of LDT decision-making and maximising the facilitation of true will decision-making by the donor, and indeed the recipient. One of the approaches of interest here is that adopted in the Dublin centre where both a counsellor and an information officer are available to help donors, recipients and family members.

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<sup>132</sup>Twelve Kidney Donors, *J Am Med Assoc*, 1968, 206, 2703-2707 at 2706.

<sup>133</sup>Gift of Life, *Wiley and Sons*, 1977 at 431-3.

<sup>134</sup>Twelve Kidney Donors, *J Am Med Assoc*, 1968, 206, 2703-2707 at 2706.

<sup>135</sup>R.G.Simmons et al., *Gift of Life, Transaction Books*, 1987



Not nearly enough is known about why LDT is chosen in the first place, and hence the rationale of using it - say in preference to CDT. Obviously medical factors will exclude some people from being donors. From, the limited number of instances where other factors at work were made explicit, it is clear that social perceptions of who is the most appropriate person to donate can be influential as can viewpoints as to efficiency of the family unit, psychological strength or weakness of individual members and anticipated refusal. There was no clear evidence of the 'black sheep' phenomenon operating within this study. The choice of LDT over cadaveric was often associated with the clinical superiority of LDT in general or in the specific case (e.g. where identical HLA match of prospective donor and recipient).

The questionnaire methodology was not sophisticated enough to bring out a holistic picture of why LDT was preferred. However, it must also be stated that even when a more open-ended interview style was adopted donors and recipients were typically unable to present a comprehensive picture as to why LDT was preferred. This in itself could be seen as a finding; being indicative of a lack of sophistication in reasoning during the decision-making process. In the worst case scenario we could perhaps be witnessing a simplification on the part of some donors which is something like as follows, "the recipient is ill, I can make him or her better, therefore I will help." At best it is still probably that the majority of donors are not sufficiently weighing up the pros and cons to decide beyond reasonable doubt that LDT is the best option.

Clearly there is a need for future European study developing extra questions to derive additional information on motivational aspects of the decision-making process. To really address the issues there may also be a need for a more sophisticated methodology - for example interviews before, during and after donation of the prospective donors, recipient and other key family members. To fully adopt this methodology researchers will have to work over a longer time scale than the EUROTOLD project and bridge the issues of getting several centres to agree to access of their prospective interviewees when such a time consuming, rigorous and potentially exposing methodology is being utilised. What may be clearly stated at this point is that enough evidence of concerns about the process have emerged to warrant more thorough attention being placed, in regulation and centre protocols, on ensuring donor informedness and testing donor motivations (for recommendations to this end see chapter 11.4).



This was one of the few studies deriving significant information of attitudes of donors and recipients towards different classes of donor in LDT. Attitudes were very liberal - more so than those of practitioners. The most poignant example of this was that as many participants expressed views in favour of strangers donating as those who expressed views against. It must be doubted whether such a view will ever be replicated amongst practitioners. The EUROTOLD study found that 3.5% (or less) of practitioners would consider strangers (represented within the term 'other' in chapter 10.2.3.4). Only 15% of practitioners in the USA, which has traditionally been more forthright on these issues, would consider stranger donation in Spital's most recent survey.<sup>136</sup> Although many donors and recipients would consider buying an organ for a relative in need it is clear from the sample interviewed that they are against the buying and selling of organs in general. This is consistent with the attitude of the general population.<sup>137</sup>

The issue of compensating donors for losses associated with donation is clearly much more than a theoretical one with donors suffering real financial hardship in practice (and sometimes the recipient by compensating the donor suffers hardship). This finding is in broad confirmation of Westlie *et al's* study discussed in chapter 8.<sup>138</sup> Further research in this area, including a more in depth look at the post-transplant economic consequences of donation. However, there is enough evidence to warrant countries taking legislative action to assure the economic rights of donors.

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<sup>136</sup>A.Spital, Unrelated Living Kidney Donors, An Update of Attitudes and Use Among U.S. Transplant Centers, *Transplantation*, June 1994, 57(12), 1722-1726

<sup>137</sup>See studies in chapter 7.

<sup>138</sup>L.Westlie et al., Quality of Life in Norwegian Kidney Donors, *Neph Dial Trans*, 1993, 8, 1146-1150.



## **Chapter 10 Professional Attitudes and Practice in LDT.**

### **10.1. Introduction.**

Attitudes towards transplantation have been investigated in a large number of studies which have, for instance, surveyed population attitudes, the attitudes of recipients, intensive care units and attitudes of transplant professionals.<sup>1</sup> However, there has been a much more limited field of studies concerning LDT specifically. These have been discussed in the previous chapters, including Spital's surveys on attitudes of US transplant centres to LDT.<sup>2</sup>

### **10.2. The EUROTOLD Questionnaires.**

#### **10.2.1. Introduction.**

The EUROTOLD Project Management Group collaborated to produce 2 main questionnaires. The first of these, a European Transplant Centre Questionnaire, contained both factual questions pertaining to transplant practice and questions about centre policies towards LDT. The second questionnaire, entitled the 'Attitudes Towards Living Donation Questionnaire', focused around hypothetical clinical scenarios with multiple choices given to respondents to select from as solutions. This was designed to test current attitudes in action and also to see how well these correlated with centre policies.

The questionnaires were worked-up in 1993 and 1994 in consultation with the whole management group which included a psychiatrist/nephrologist (Peter Veitch), a clinical psychologist (Christine Cordle), a transplant surgeon (Peter Donnelly) and a transplant co-ordinator (Anne Simpson). External expertise was drawn on, including that of the Oslo transplant centre - in particular Arnt Jacobsen. In 1995 the questionnaires were

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<sup>1</sup>See e.g. G.Schutt and P.Schroeder, Population Attitudes Toward Organ Donation in Germany, *Trans Proc*, 1993, 25(6), 3127-3128; J.L.Stark, P.Reiley et al., Attitudes Affecting Organ Donation in the Intensive Care Unit, *Heart and Lung*, 1984(July), 13(4); H.Gabel and K.Lindskoug, A Survey of Public Attitudes Toward Cadaveric Organ Donation in a Swedish Community, *Trans Proc*, 1988, 20(3), 431; A.M.Munster, R.E.Stengle, M.Clinton Miller III, Community Attitudes to Renal Transplantation, *Am J of Surg*, 1974, 128, 415-418. For further studies see chapter 2.

<sup>2</sup>E.g. Unconventional Living Kidney Donors - Attitudes and Use Amongst Transplant Centres, *Transplantation*, 1989, 48 (August), 243-248 and Unrelated Living Kidney Donors, An Update of Attitudes and Use Among U.S. Transplant Centers, *Transplantation*, 1994, 57(12), 1722-1726.



distributed across Eastern and Western European Countries. Questionnaires were sent to 190 transplant centres representing 27 countries across Europe. The Centre Questionnaire was designed to elicit a whole centre response and was completed by Centre Directors, often collaboratively with their medical teams. The Attitudes Questionnaires was designed to be answered by all different transplant personnel within each European centre. Responses were received from a wide variety of personnel including surgeons, nephrologists, anaesthetists, transplant co-ordinators and nurses. In some instances the questionnaire was filled in collaboratively and returned as a 'centre' rather than individual attitude response.

The Centre Questionnaire was cross correlated with the Attitudes Questionnaire, the result being a confirmation of the internal validity of both questionnaires. Underlying this cross correlation was the development of a numerical coding system for attitudes questionnaire responses (see Appendix 3A(vi)). A scaling for attitudes from liberal to restrictive was developed in each of the 4 key areas, comprising:

- attitudes with regard to use of dialysis / transplantation;
- attitudes with regard to age matching;
- attitudes to dialysis / pre-dialysis; *and*
- attitudes toward related / unrelated donors.

The two questionnaires were complemented by the development of a scoring system for laws.<sup>3</sup> A numerical system was developed (see Appendix 3A(v)) with a scaling for LDT law according to restrictiveness / liberality on the following 8 points:

- basic clinical conditions in which living donation takes place;
- restrictions on living donors who are not close genetic relatives of the recipient;
- restrictions on risks / consequences a donor can be exposed to;
- the combination of 1 to 3 as the basic legal framework of restriction of clinical judgment;
- restrictions on the use of minors;
- the status of the law in terms of it's completeness in considering the various aspects of LDT;
- provisions considering financial compensation of the donor; *and*

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<sup>3</sup>Complementing the LEGISEARCH database developed by David Price and I.



- the length of time the law has been in existence.

Actual laws across Europe were then scored in these 8 areas according to their points on the scale; the more positive a score the more permissive the law on organ LDT, the more negative the more restrictive (see Figure 7).

**Figure 7: Coding of LDT Laws**

Country And Code	Clinical Conditions	Restrictions On Non Closely Related Donors	Restriction On Risks	Minors	Status of Law	Compensation For Financial Losses	Overall
1 Albania	0	0	0	0	-2	0	-2
2 Austria	0	0	0	0	-2	0	-2
2 Belgium	-3	0	0	0	2	3	2
3 Belarus	0	0	0	-2	1	0	-1
3 Cyprus	0	0	0	1	2	0	3
3 Denmark	0	0	-1	1	2	0	2
1 Eire	0	0	0	0	-2	0	-2
1 Estonia	0	0	0	0	-2	0	-2
3 Finland	0	0	0	-2	2	2	2
3 France	0	-2	0	-2	2	2	0
1 Germany	0	0	0	0	-2	0	-2
3 Greece	0	0	0	-2	2	0	0
3 Hungary	0	0	-1	1	2	0	2
1 Lithuania	0	0	0	0	-2	0	-2
1 Norway	0	0	-1	1	2	0	2
2 Poland	0	0	-1	-2	2	0	-1
2 Portugal	0	-1	1	-2	2	2	2
2 Romania	0	-2	0	-2	2	0	-2
2 Rus. Fed.	-3	-3	-1	-2	2	0	-7
3 Spain	0	0	0	-2	2	3	3
2 Slovakia	-2	0	0	-1	1	1	-1
2 Slovenia	-2	-1	0	-2	2	3	0
3 Sweden	0	0	0	1	2	0	3
3 Turkey	0	0	0	1	2	0	3
Netherlands	0	0	0	0(-2)	-2(2)	0(3)	-2(3)
3 Switzerland	0	0	0	0	1	1	1
3 U.K.	0	-1	0	0	1	1	1



This legal coding system is unique in the transplantation field, although similar systems have been used in analogous contexts including a study of the effect of legislative requirements relating to informed consent on breast conservation surgery across different jurisdictions in the USA.<sup>4</sup> Scores for laws were cross correlated with results in both the Centre and Attitudes Questionnaires to test if there was any positive or negative correlation between the liberality / restrictiveness of the legal framework and attitudes and practice in transplantation both in general and on specific points (e.g. use of minors etc.).

Both the legal and attitudes questionnaire scoring systems were developed through considerable discussion in the EUROTOLD management group and are based on reasoned and clear criteria but inevitably slightly different interpretations could have been made with equal validity. The scoring systems are in effect approximate and accordingly results are approximations.

### **10.2.2. General Results.**

#### **10.2.2.1. Questionnaire Responses.**

Of the 190 transplant centres appraised in 26 countries 56% of centres responded. This is a similar response rate to the 1996 EDTA report.<sup>5</sup> There were no responses from 7 countries these having a combined total of 14 centres (Bulgaria (2) Slovenia (1), Finland (2), Eire (1), Luxembourg (1), Turkey (2), Portugal (5)). There was a 78% response rate from the transplant centres in the remaining 20 countries. The responding centres covered a total of 211.3 million population in Europe with the catchment area of individual centres ranging from 0.5 million (Cyprus) to 10 million (Romania).

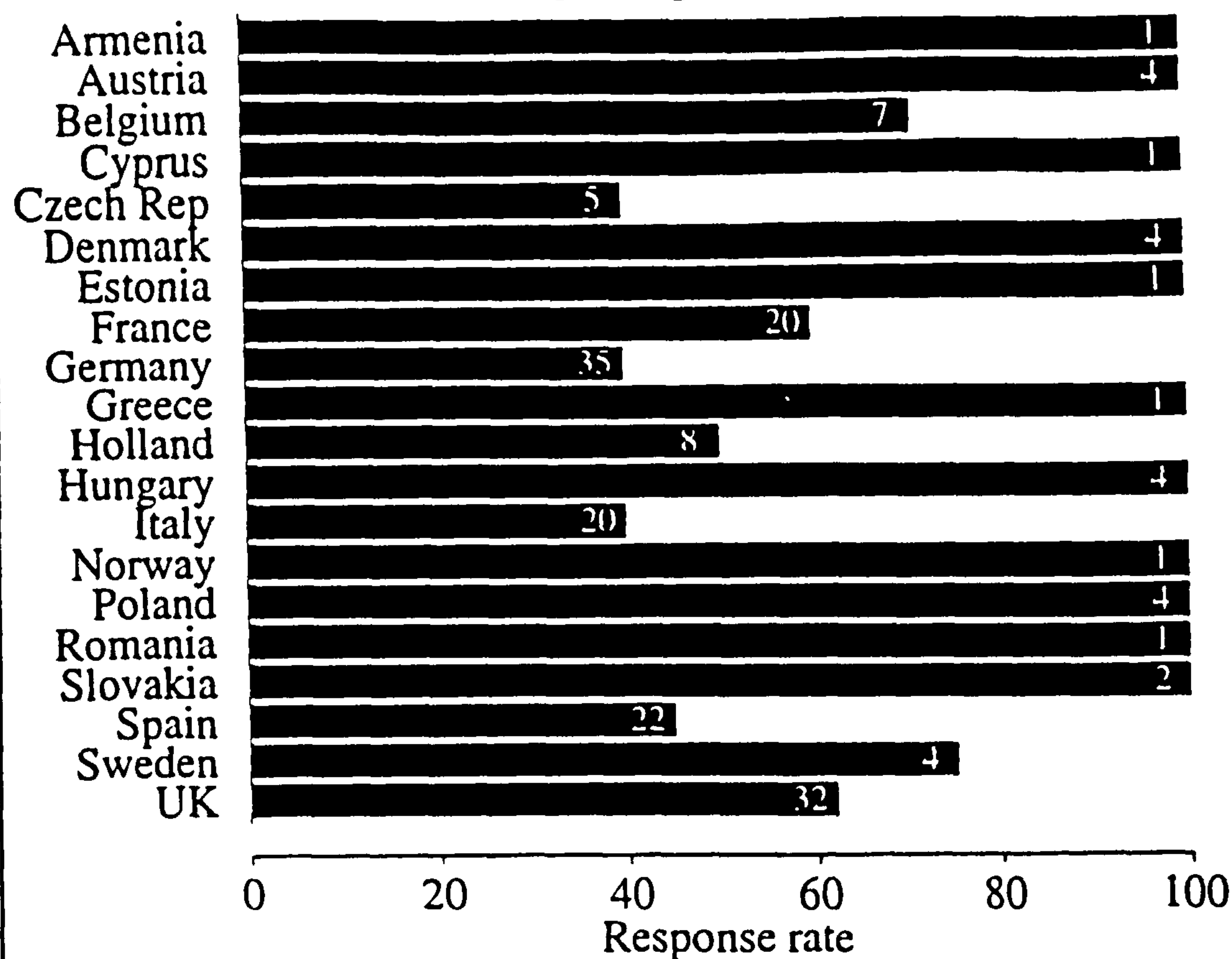
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<sup>4</sup>*New England Journal of Medicine*, 335(14), 1035-1040. See also a study using coding in the context of advance health care directives (*Journal of Law, Medicine and Ethics*, 24, 108-117).

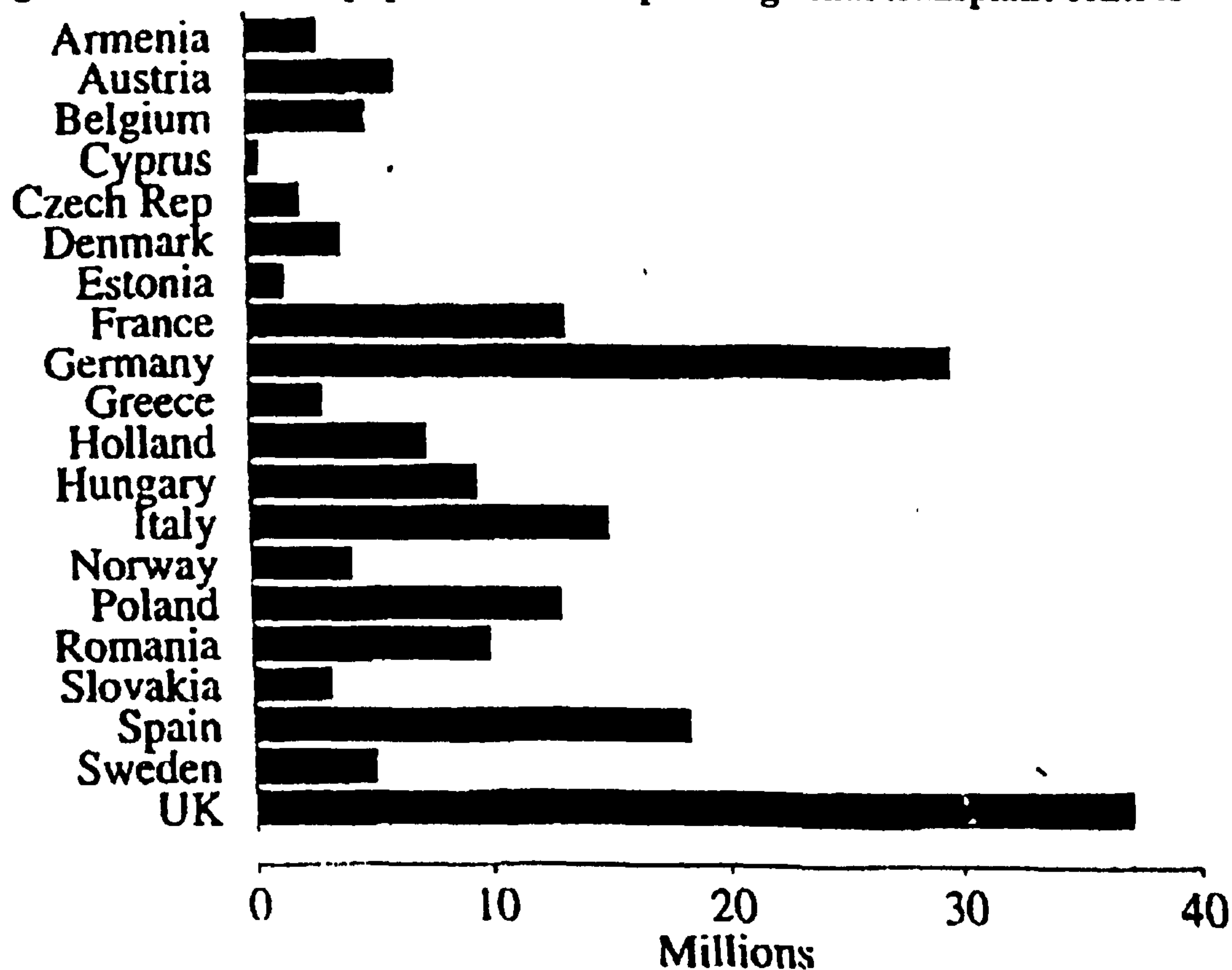
<sup>5</sup>62% response, Valderrabano et al., Report on Management of Renal Failure in Europe XXV, 1994 End Stage Renal Disease and Dialysis Report, *Neph Dial Trans*, 1996, 11(Suppl 1), 2-21.



**Figure 8: Number of Centres Responding**

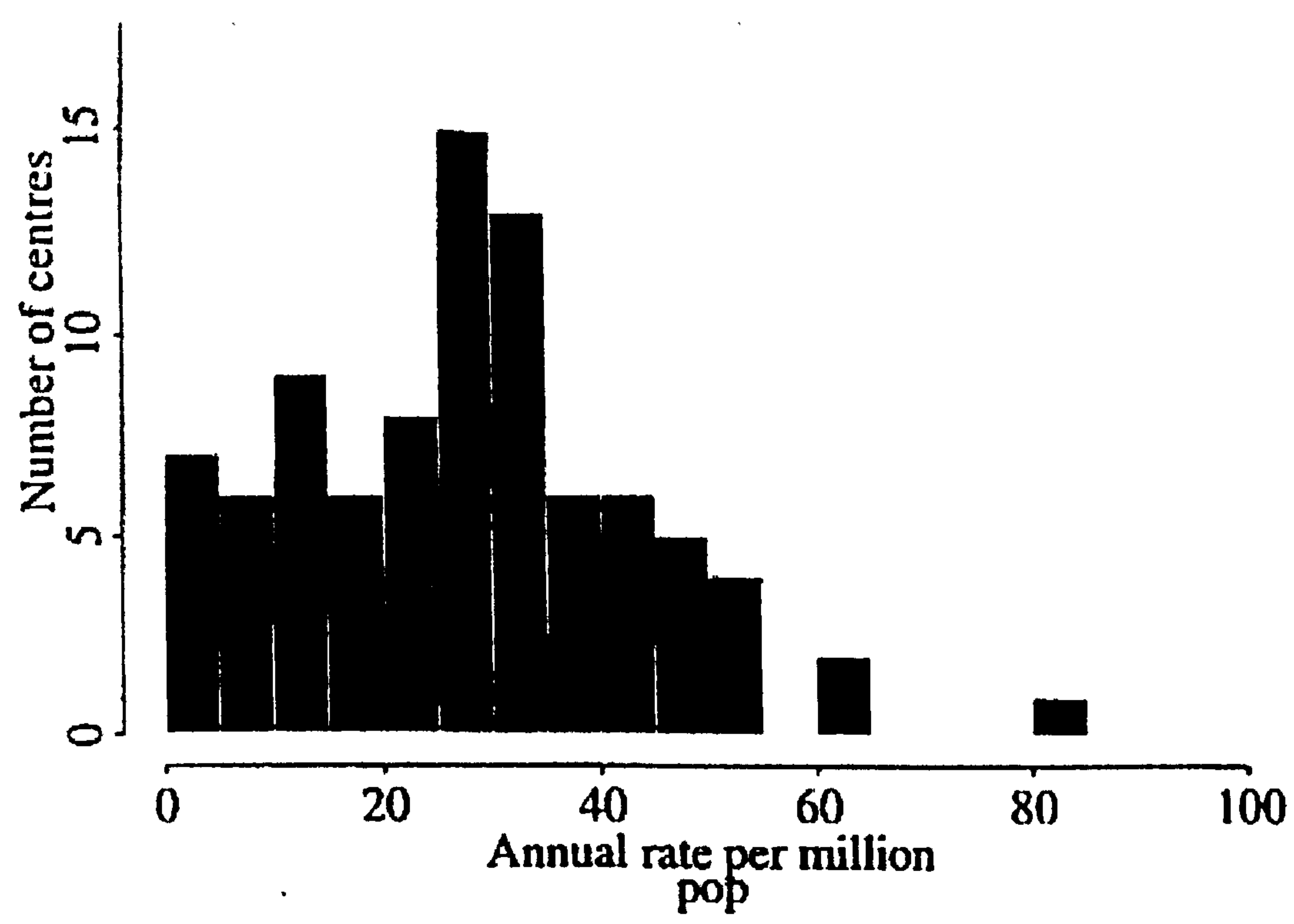


**Figure 9: Catchment populations of responding renal transplant centres**

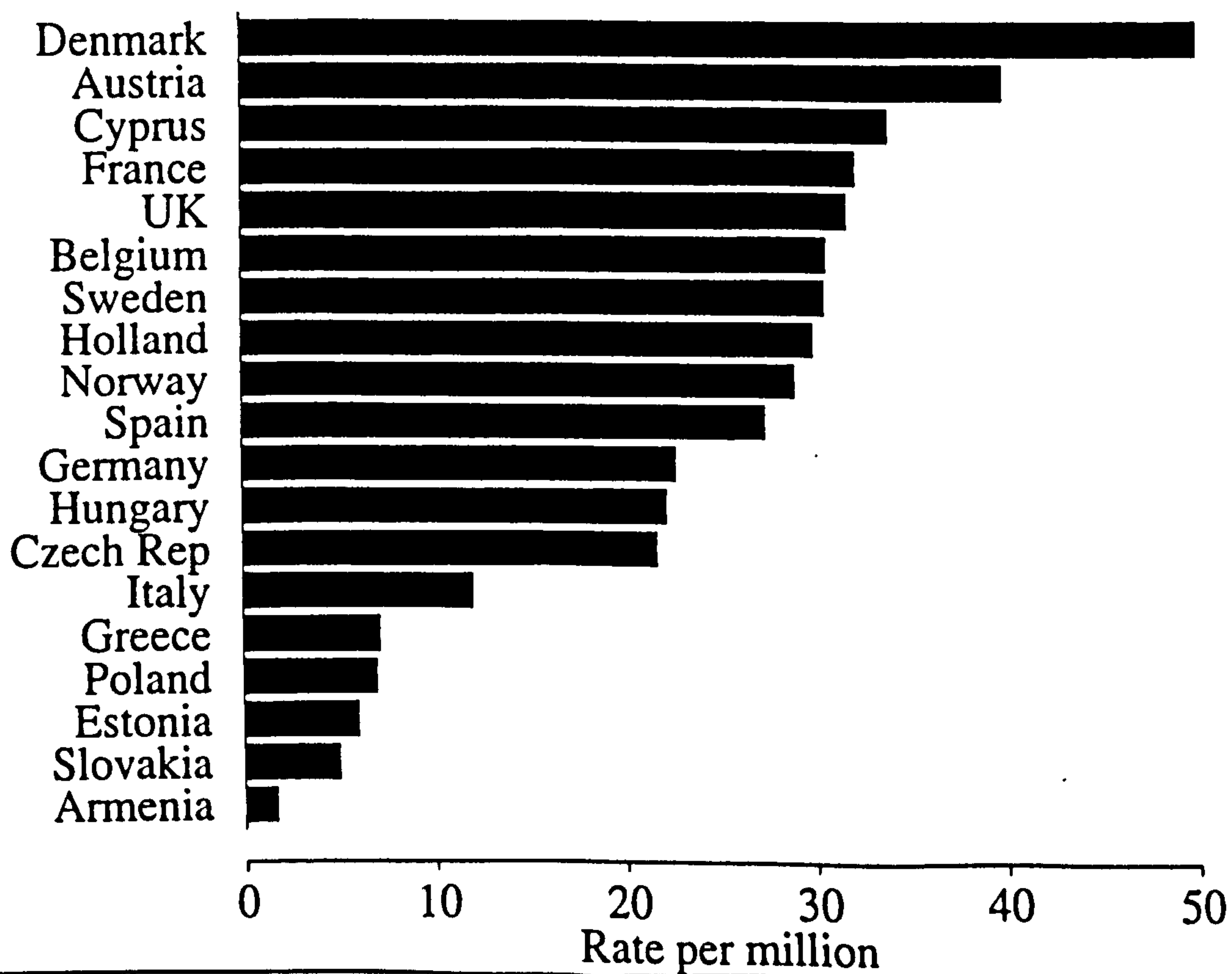




**Figure 10: Transplant rate per million population of responding centres in 1993-4.**

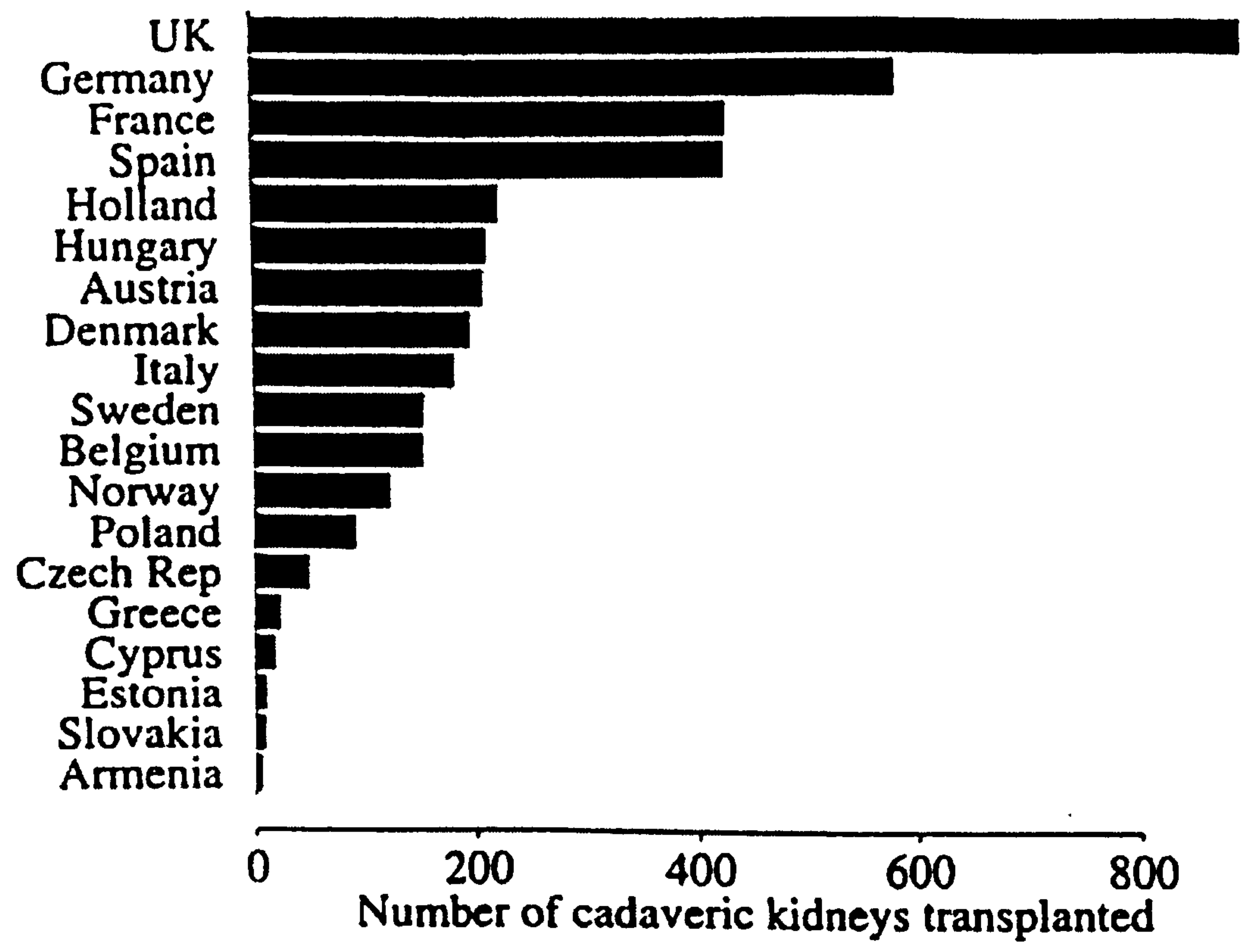


**Figure 11: Cadaver transplant rates in responding centres (by country)**

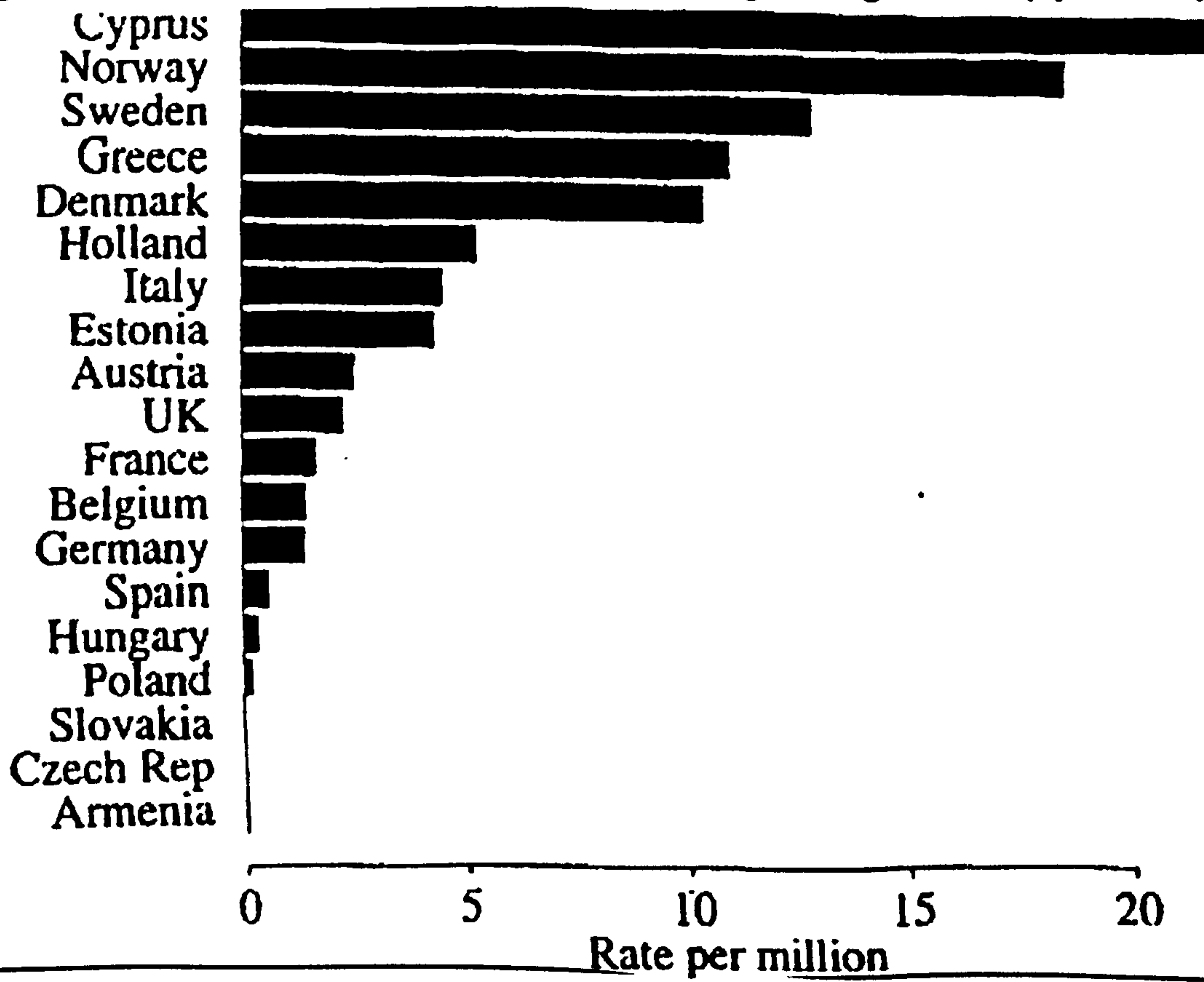




**Figure 12: Number of CDT's performed in responding centres (by country) in 1993.**

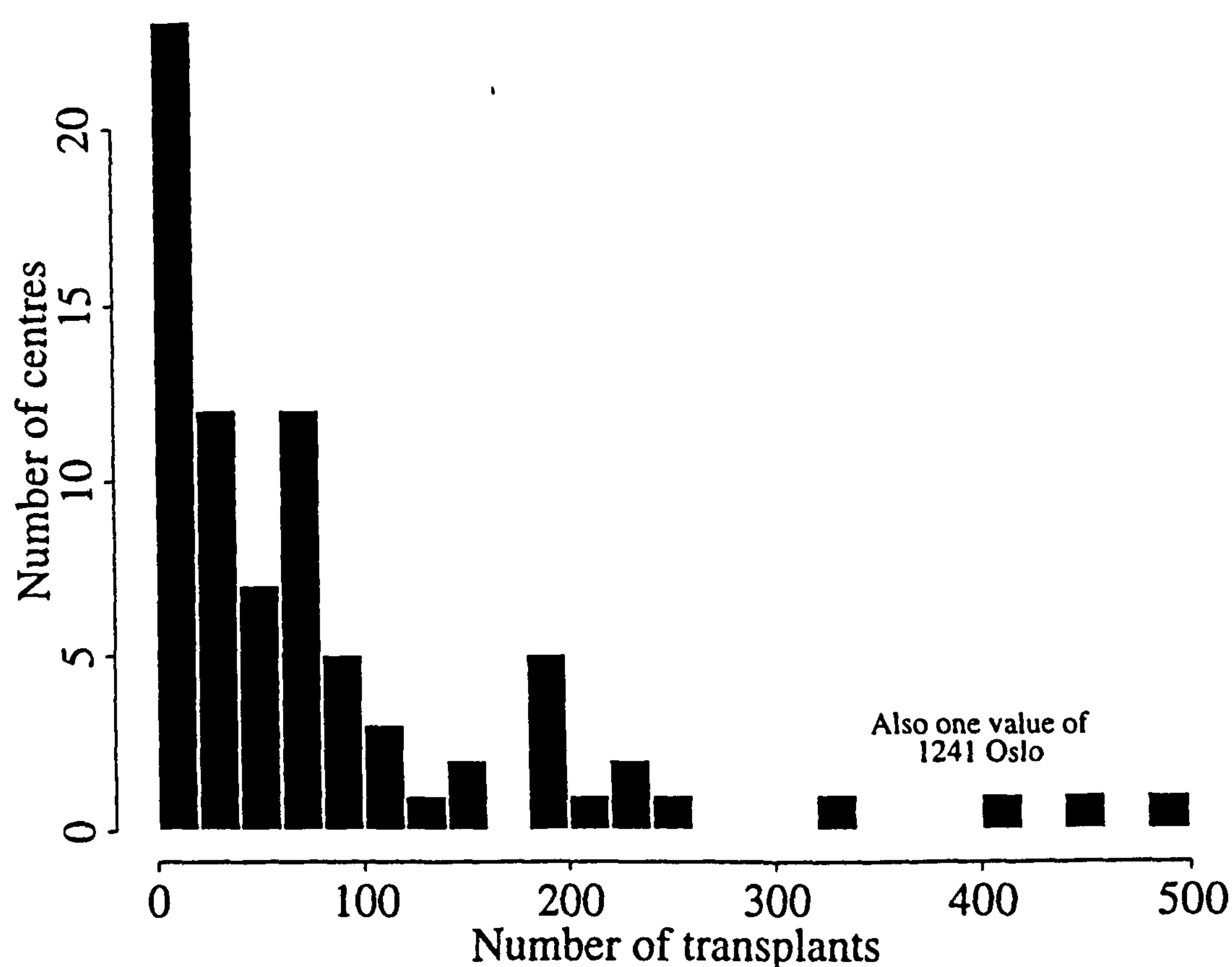


**Figure 13: Living donor transplant rates in responding centres (by country) in 1993**





**Figure 14: Cumulative total of living donor transplants in responding centres (by country)**

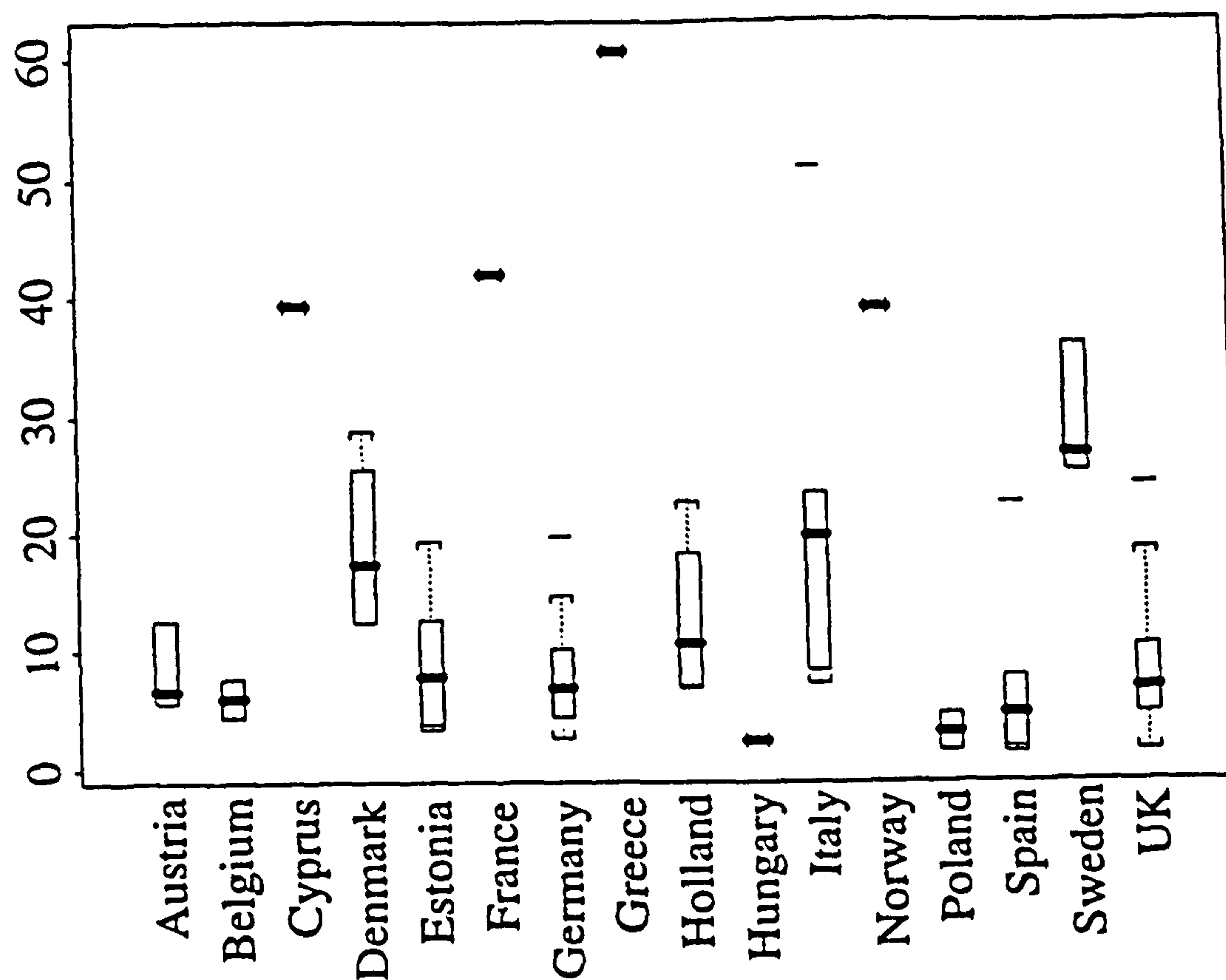


86% of responding centres had an LDT programme (85% when weighted by catchment population). In the year of the survey, Slovakia, Czech Republic and Armenia respondents were not performing LDT's. At the other end of the scale one centre (Cyprus) had an LDT rate p.m.p. of above 20.

One of the limitations of the questionnaire was that it was not translated and this may have contributed to a low or non-response from some countries. Non-response of some centres may also be attributable to more negative attitudes towards LDT, although it was stressed in accompanying letters sent out with the questionnaires that the objective was not to promote living donation but to obtain an accurate understanding of practice and attitudes.



**Figure 15: Proportion of total kidney transplants involving living donors**



#### **10.2.2.2. The Possibility of Expanding Use of LDT.**

96% of the responding centres answered the question of whether they foresaw an expansion of their living donor programme. Of those answering 55% said "yes", 10% said "no" and 29% said "maybe." From this an expansion in LDT use may be forecasted. Results were even more impressively favourable to expansion when weighted by catchment population (respectively 66%, 28% and 6%). However, due to caution on the part of clinicians, positive attitudes are not always fully reflected in increased usage of LDT. Of figures for responding centres in the Centre Questionnaire, the totals in Estonia, Denmark and to a lesser extent Austria demonstrated a trend of increased usage of LDT in relation to total transplant activity whilst figure for Belgium and Spain showed the opposite.



### 10.2.2.3. Cadaveric and LDT vis-à-vis Dialysis.

40% of responding centres would consider cadaveric transplantation before dialysis. 51% would consider cadaveric transplantation when dialysis was needed and 9% only when the patient has been on dialysis for some time. General quality of life and economic benefits of transplantation over dialysis were reflected in 91% of respondents being prepared to consider transplant before dialysis or when it is needed. The rationale of 9% of respondents only doing cadaveric transplant after the patient has been on dialysis for some time is difficult to understand; it would be difficult to justify on grounds of clinical work-up because results tended to indicate that pre-dialysis transplantation is the "gold standard."<sup>6</sup>

For centres with a living donor programme 60% considered LDT before dialysis, 29.33% when dialysis was needed and 10.67% after a period of dialysis. These results are similar to those provided for cadaveric vis-à-vis dialysis and are surprisingly positive in the sense that active LDT centres are generally prepared to consider the clinical benefits of pre / at-dialysis with no rigid rule that living donation should only be used in the last resort. These centres would appear to have assessed that the ethical problems of using living donors do not *per se* outweigh clinical advantages of pre-dialysis living donation. The logic is that if one is using LDT the most benefit may as well be derived by using it pre-dialysis. Some centres are taking a pragmatic go-ahead attitude that with long waiting lists LDT should be used as soon as possible where it is a good option. The counter-perspective would be that what matters is not the general waiting list but only using LDT as a last resort in an individual situation e.g. where patient health is deteriorating and the possibility of finding a cadaveric donor is low. From a donor perspective the former approach moves somewhat in the direction of emphasising overall utility, although this could be tempered by imposing a requirement for the LDT to be justified as better than an average cadaveric match. It could be an acceptable approach providing it is transparent to the prospective donor who could be told something to the effect of "your donation will be of overall benefit by reducing the waiting list for CDT. We are suggesting doing an LDT now because it is the best time to do it. However, you may decide it is better to wait to see if a good cadaveric organ turns up within a reasonable space of time."

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<sup>6</sup>Confirming P.K.Donnelly's view in 'Pre Dialysis Living Donor Renal Transplantation - Is it Still The Gold Standard for Cost, Convenience and Graft Survival?' *Trans Proc*, 1995, 27(1)).



The Attitudes Questionnaire also produced results relating to pre-dialysis transplant with a scoring system being devised to analyse liberality of attitude towards pre-dialysis transplant. There was little difference in attitudes towards pre-dialysis between different medical specialities. A small correlation (.233) was found between the centre living donor rate per million population and attitudes toward pre-dialysis. This could be explained as the more 'adventurous' centres being the ones who do more living donation p.m.p. Pre-dialysis was significantly more favoured (T.test=5.402 p=0) by those centres with a living donor programme (mean sd score 2.94 3.16) than those without (-.23 3.1). This was fairly predictable. Countries with the most favourable attitude towards pre-dialysis transplantation were Cyprus, Norway, Italy, Sweden, Holland and Albania (all 5.0), those with the most restrictive attitudes were Belgium (0.6), Spain (0.8), Slovakia (1) and Hungary (1.1). Norway is an example of a country with a more favourable attitude towards pre-dialysis transplantation which has a deliberate policy of transplanting patients as soon as possible. On the whole the countries with the most favourable attitude toward pre-dialysis significantly rely on LDT. Equally countries having a more restrictive attitude to pre-dialysis typically have low reliance on LDT.

Scoring was also developed to analyse the overall results of the Attitudes Questionnaire for positive attitudes toward transplantation vis-à-vis dialysis. Countries with the most favourable attitude towards transplanting were Cyprus (11), Norway (10), Italy (7.4), Poland (5.3) and Armenia (5) with the least favourable being Belgium (-5.4), Spain (-4.2), Hungary (-3.3), Romania (-3) and Germany (-3). Some of these results are not surprising - for instance the fact that Norway was positive and Germany one of the least favourable is correlative with transplant rates in these countries (see Graphs 17 and 18 respectively). However other results are difficult to interpret, such as Belgium and Spain which have very high rates of transplantation in practice (Graph 17). Despite extremely low use of transplantation, Italy and Poland have very positive professional attitudes to transplantation. This suggests the obstacles to further developing the programme lie elsewhere (e.g. political and public attitudes respectively). The more favourable attitudes were positively correlated (.217) with centre rates of living donation p.m.p. and not surprisingly more favourable attitudes were found (T-test=5.796 p=0) at centres with a living donor program (0.38 7.44) than those without (-7.63 7.33). As between specialities there was some evidence that nephrologists had a less liberal attitude (0.7 7.5) than surgeons (1.8 8) and other professionals (1.1 8.6) but this was not statistically very significant. The more positive attitude of surgeons is not surprising.



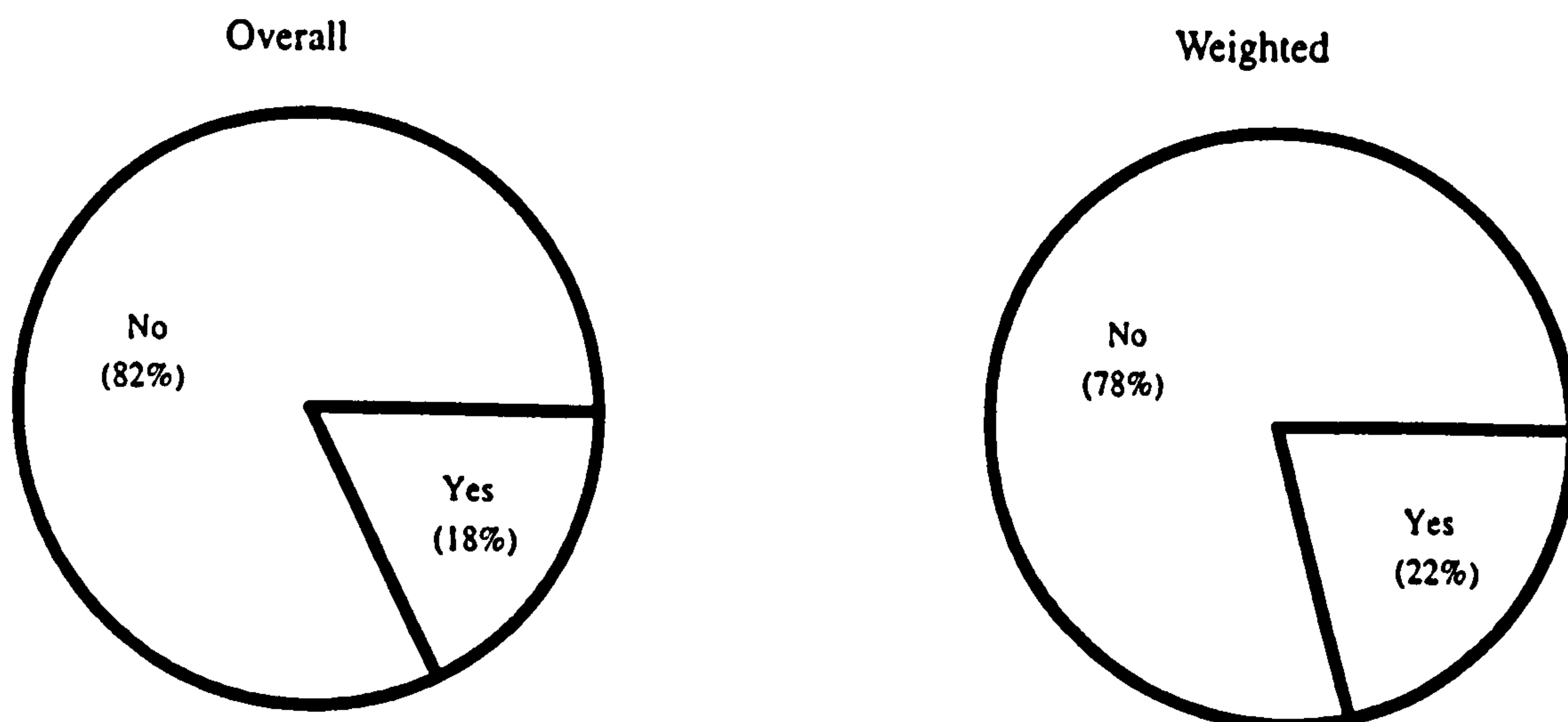
### **10.2.3. Results Related to Ethico-Legal Aspects.**

#### **10.2.3.1. Basic preconditions for Conducting LDT.**

##### **Legality of LDT.**

Respondents answered the question did they consider LDT was legal. In Spain 5 out of 10 respondents felt it was not, in Italy 3 out of 8, in France 2 out of 12, in Belgium 3 out of 5, in Austria 1 out of 4 and in Germany 1 out of 14. LDT is in fact legal in all these countries, the perception that it is not may indicate some confusion as between restrictions on LDT and it's outright illegality. There may be a need for a more positive framework of expression of when LDT is legally permissible. Comprehensive LDT law in Austria, Italy and Germany would be useful here and more generally codes of practice / guidance could be further developed on the national level, as for instance have accompanied the passing of HOTA 1989 in the UK. A correlation (.2694 statistically significant at 5%) was established between whether or not LDT was considered legal by centres and the status of LDT law (as regards its completeness), it's overall clinical restrictiveness / liberality (.3468 significant at 0.1%) in the jurisdictions the centres respectively came under and the length of time the law was in place (.2206 significant at 5%).

**Figure 16: Centres response to whether the law of their country prevents the use of living donors**





Whether or not an expansion in living donation was foreseen by centres was negatively correlated with the status of LDT law (-.362 significant at 5%). Interestingly there appears to be no correlation between a well developed law and the foresight of more expansive use of LDT although, as discussed below, there is a correlation between a clinically law which is liberal with regard to basic preconditions applied to conducting LDT and the foresight of expansion of LDT.

### Clinical Conditions Applied to LDT

Most laws leave the question of HLA match to clinical discretion. More than half (54.14%) of responding centres with a living donor programme had a centre policy of requiring a minimum HLA match (although this was only 46% when weighted by catchment population). The majority of centres 80% - 81% when weighted by catchment population) tissue type and cross-match all prospective donors that have an ABO blood match. There was no strong correlation found between legal requirements as to the clinical conditions within which LDT occurs and clinical exclusion criteria applied to LDT by responding centres. This is not entirely surprising since law generally imposes non-stringent requirements based largely on ethical imperatives leaving specific clinical issues to be determined by transplant centres or national codes of practice. Nevertheless, a correlation (.32) was established between the liberality / restrictiveness of law with regard to restrictions on the exercise of clinical judgment and whether or not centres with a living donor programme foresaw its expansion. In other words the clinical framework within which LDT (although not stringently regulated) can legally be maybe impacted by or have an impact on attitudes about use of living donation.

A correlation was also established (.2921) between attitudes towards pre-dialysis in the Attitudes Questionnaire responses and the legal scoring on basic preconditions for conducting LDT. Whether this is positive practitioner attitudes towards pre-dialysis transplantation being reflected in the law, or a liberal law helping to generate more positive attitudes, is hard to say. This is something of a chicken and egg argument but it may be tentatively concluded that law could be used as a tool to promote more expansive, or indeed restrictive, attitudes towards LDT.

Maximum age criteria are usually applied in transplantation practice but generally not prescribed within transplant laws. This survey shows considerable variations in maximum ages prescribed on a centre by centre basis (for centres with an LDT



programme only). Maximum ages varied between 60 and 80 with the Norwegian centre (Oslo) having no maximum age limit. It is surprising that age criteria are generally a centre rather than national policy matter. 20% of units matched for age, which again is a centre policy rather than something decided on a national or legal basis.

#### **10.2.3.2. Informed Consent.**

67% of centres with LDT programmes had a protocol for evaluation of donors (73% when weighted by catchment population) but only 37% had written guidelines as to use of living donors (49% when weighted by catchment population). A protocol and written guidelines, if more universally adopted, would assist in developing a methodical approach to living donation within which it could be ascertained to a certain extent that ethical and legal concerns as to both informedness and voluntariness of consent had been addressed.

#### **10.2.3.3. Minors, Adults and Capacity.**

##### **Non-age Related Mental Capacity**

What appears to be the case is that donors are not routinely tested for questionable capacity on grounds of mental illness or disability in the majority of centres. Only 31.4% of centres with a LDT programme undertake a donor psychiatric/psychological evaluation (41% when weighted by catchment population). Presumably in other centres the evaluative process may occur in a more informal way with the possibility of a psychiatric expert being brought in where the competency of the donor is not clear.

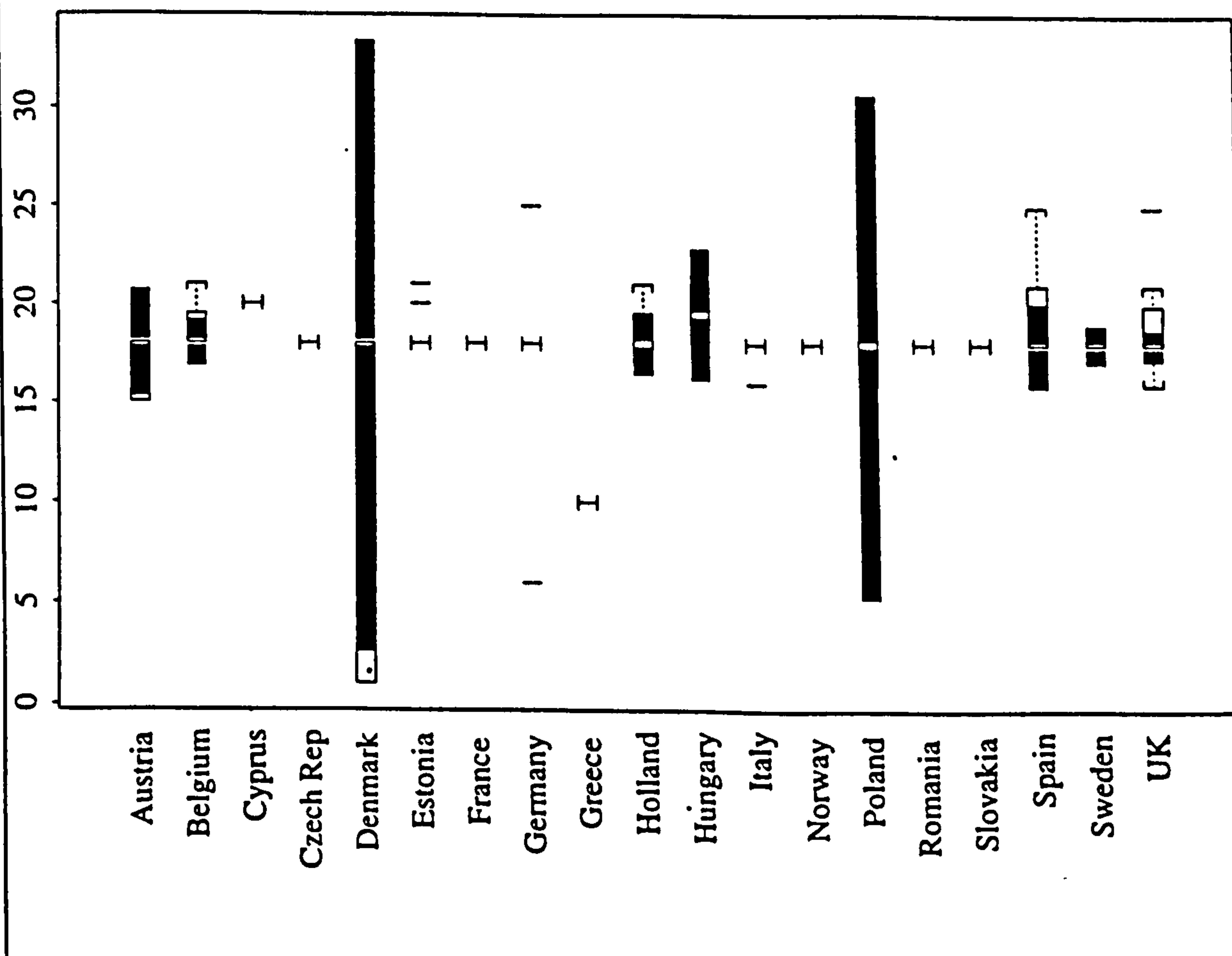
##### **Use of Minors.**

Centres responded on a question asking them the minimum and maximum ages at which they would consider living donations. There were no significant attitude differences discovered between different medical specialities with regard to acceptable minimum age for donors. The range of minimum's within individual centres was 1-30 years. It is bizarre that a 1 year old could be considered old enough by a centre to be a living donor and that conversely a 29 year old could be considered not old enough. Analysis of this question in greater detail reveals that one centre put forward a minimum age of 30, a second put forward 25. One centre put forward 1 as a minimum age and one centre put



forward a minimum age of 6! Removing these four centres the spread is 10-21. However of the remaining centres it could be stated that those not allowing 18-21 year old donors are overly paternalistic. Conversely the principle of informed donor consent is probably not being applied in situations where the donor is 10 years old; a person is unlikely to be able to give a proper understanding and meaningful agreement to LDT at that age.

**Figure 17: Minimum Donor Age (if specified)**



The legal scoring system indicates that more recent legislation tends to be more restrictive than older legislation as regards prescribing conditions for minor LDT. This is less likely to be a deliberate attempt of laws to make the position more restrictive than the fact that old laws tended to be less restrictive simply through the absence of specifically paying much attention to minor LDT. A negative correlation (-.433 which is statistically significant at the 0.1% level) was established between minimum ages of donor accepted in centres (centre questionnaire) and the restrictiveness / liberality of law on minors



(under the respective jurisdictions of the centres). It is most surprising that there is no apparent link between practitioner minimum age criteria and legal minimum age criteria; in other words legal policy apparently does not correlate to policy/practice of clinicians.

The Attitudes Questionnaire had one question relating to minors as follows;

"a 14 year old boy has been on haemodialysis for 3 years but is experiencing severe psychological problems with needling. He is unsuitable for CAPD as a result of previous urological surgery as an infant. His mother is a single parent with three other children, one of them being his identical twin. This patient reacts strongly to mother on cytotoxic crossmatch as a result of a previous transfusion."

Respondents chose from 3 alternative solutions as follows; accept the twin 36%, await a good cadaver match 39% and await a blood group compatible cadaver graft 25.4%. Clinically speaking the twin is almost the perfect choice bearing in mind the clinical need for transplantation to occur as soon as possible and the fact that it would provide approximately 4 times the graft survival expectancy of an average cadaveric graft. If such a clinically perfect choice of 14 year old is rejected by two thirds of transplant professionals it can probably be stated these professionals in Europe will never use minors of 14 or younger. A minority of professionals would use such minors in a 'clinically perfect' situation such as this but it is uncertain whether or not they would use them were the clinical benefits less exceptional. This more liberal attitude in the United States to minors around the age of 14 is notable<sup>7</sup> - as is the more liberal practice. Why the reluctance to use 14 year old twins in Europe when they are a magnificent form of LDT in terms of prospective graft outcome? There may be both concerns about how to test for capacity and the need to be seen to make 'safe' decisions.

#### **10.2.3.4. Use of Different Classes of Donor**

Respondents with an LDT programme answered the question of who they would consider as a living donor as follows: Parents 98.8%, Siblings 98.8%, Spouse 54.5%, Relative by Marriage 23%, Grandparent 54%, Son/daughter 52.9%, Friend 10.3%, Other 3.5%. Perhaps the most interesting factor was that 54.5% of respondents with an LDT programme would consider using spouses; a percentage exceeding that for grandparents

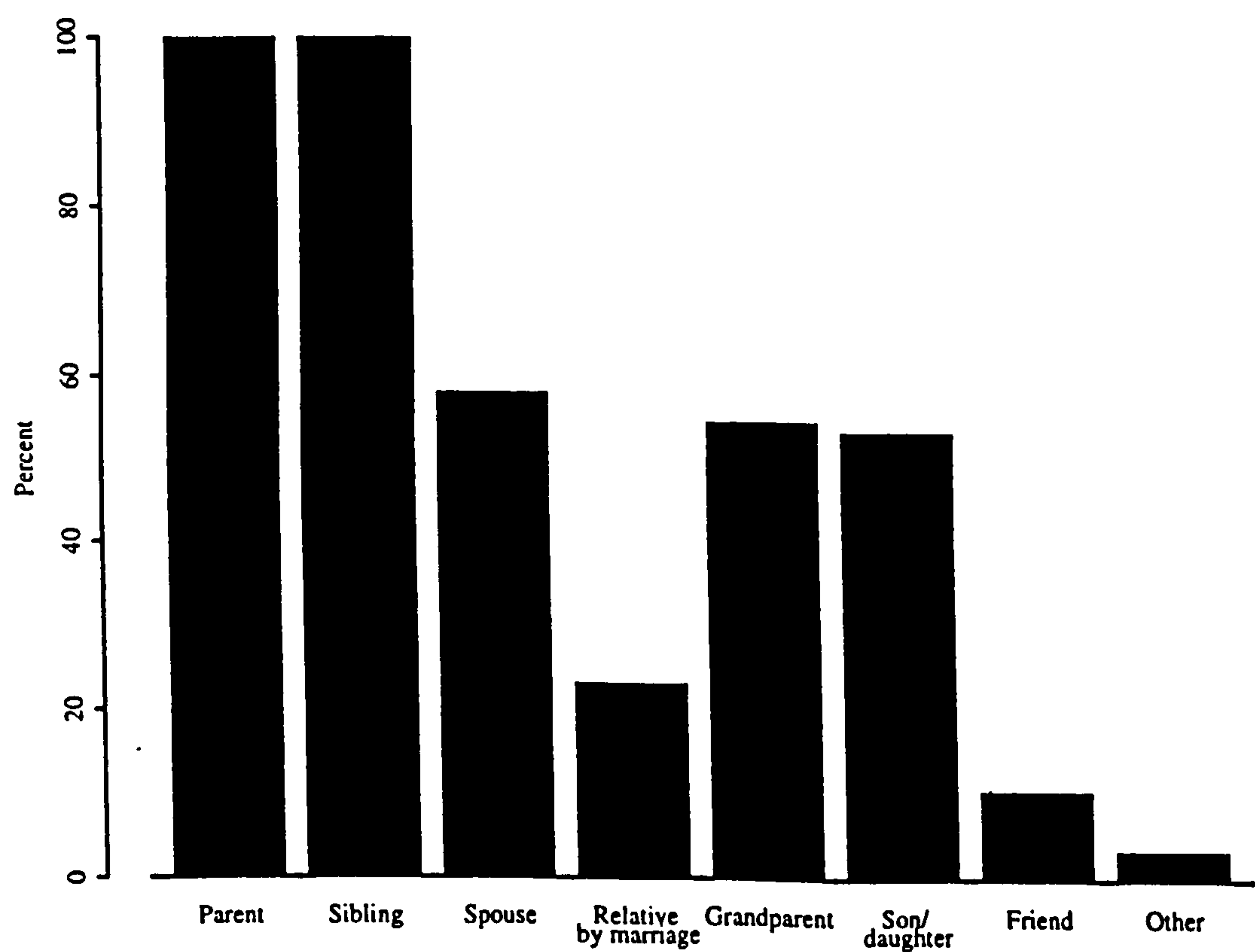
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<sup>7</sup>See Spital's results on minors presented in chapter 7.1.



and son / daughter matches. Presumably this is based on the clinical significance of age matching, with spouses tending to be a closer match and more preferable as living donors in this regard. However, age matching is clearly a secondary factor at times; parents are almost universally considered yet are not any more age matched than son / daughter donations which are not so accepted. Presumably son /daughter donations are considered to be less appropriate to donate partly on a psychological basis, in the sense that while donation by a parent is typically viewed as a natural expression of parental 'love,' donation by a child to a parent is considered more prone to being influenced by guilt etc. However, this is a somewhat socially relative perception - with people of some cultures (particularly Asian) typically viewing the family as a unit with mutual rather than more one-way caring responsibilities. Lesser use of 'offspring' donations may also be due to practical considerations such as the possibility that they may have their own dependants to look after. A closer examination of attitudes in this area would be valuable as there could be underutilisation occurring.

**Figure 18: Consideration of different classes of living donor by responding centres with an LDT programme**





Strategies to increase LURD in Europe will almost exclusively have to focus on spousal donation if they are to strike a chord with transplant centre aspirations. However, in the main it is likely that the primary increases in LDT in Europe will be achieved through increased parent and sibling donation. There was a positive correlation (.290) between centres considering spousal donation and the liberality / restrictiveness of law relating to classes of donor outside close genetic relatives. Law may be a key element in facilitating spousal donation.

The Attitudes Questionnaire also yielded useful information about different types of donor with an overall scoring system developed to analyse responses according to degree of positivity about LURD's. The most positive attitudes toward LURD's were found in Armenia (8), Slovakia (7) and Norway (7) with fairly positive attitudes found in Denmark (4.1), Poland (4), Switzerland (3.8) and Italy (3.7). Interestingly while Denmark, Switzerland and Norway have relatively high rates of LDT p.m.p. the other countries do not and so the positive attitude toward LURD needs closer examination. One possible explanation is that Italy, Armenia, Slovakia and Poland all have low rates of kidney transplantation p.m.p. and are clearly very keen to explore avenues of programme expansion. Fairly low rates of LDT at present in these countries may be more to do with organisational, financial and cultural obstacles than cautiousness amongst transplant professionals. Countries with the more restrictive attitudes towards LURD in the survey included Romania (-4), Cyprus (-3), Czech Republic (-2.8), Estonia (-2), Slovenia (-1.7), France (-1) and Belgium (-0.2). Romania's reluctance may be partly stem from having insufficient equipment to do living donations with the highest safety standards.<sup>8</sup> Cyprus has a high living donor rate which makes it's centre's relative antipathy toward living unrelated surprising. France and Belgium have traditionally adopted a more conservative stance towards living organ donation as a whole, although this appears to be somewhat changing in Belgium. The reasons for the relative antipathy toward living unrelated in the other 3 countries are not clear.

Not surprisingly those professionals (165) responding from centres with a living donor programme (mean sd score of 1.47 4.1) were found to have more positive attitudes towards LURD (T-test= 3.404 p=0.0007jp r) than those responding (35) from centres without a programme (mean sd score of -1.03 3.07). A correlation (.249) was also found

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<sup>8</sup>Professor Proca in presentation given at the Budapest EUROTOLD workshop, March 1996. However there are signs that Romania is becoming increasingly active in LDT with 12 LDT's conducted in 1996 with good results (Professor Proca, EUROTOLD communication, December 1996).



between extent of centre living donor programmes and positivity of attitudes toward LURD. No significant differences were detected in the attitudes of different specialities toward LURD.

Spital's studies<sup>9</sup> indicate that Europe is much more conservative as regards LURD in both its attitude and practice. In 1994 Spital followed up an earlier survey of the views and practices of all transplant centers in the United States regarding unrelated living kidney donation.<sup>10</sup> 64% of centers responded (127). 88% of these would accept spouses as donors, 63% would accept friends and 15% would even consider altruistic strangers. Commenting on the relationship of this study with his study 6 years ago Spital stated,

"it became clear that support for unrelated living kidney donation had increased, as the great majority of centers now believe that emotionally related donors are acceptable. On the other hand, while more of these donors are being used, they still account for only a small fraction of all kidney transplants. It appears that the medical successes and favourable ethical arguments have generated broad support for some types of unrelated living donors, but more in principle than in practice, as there still seems to be some hesitation to actually proceed."<sup>11</sup>

Although this is a true reflection of the statistics, as Spital notes there still have been changes in patterns of use. 22 of the responding centers had actually used friends as living donors compared with only 3 in the survey 6 years before, although this still only amounted to 40 such transplants in the previous year. The number of centers now using spouses was more than twice that in the previous survey. However, of the small number of centers accepting the idea of strangers as donors in principle none had actually used them in practice. Opposition appeared to revolve around the difficulties of being certain of altruistic motive as opposed to financial in such a situation and also factors like the lack of available guidelines, possibility of psychopathology and the view that it was unethical.

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<sup>9</sup>E.g. Unconventional Living Kidney Donors - Attitudes and Use Amongst Transplant Centres, *Transplantation*, 1989, 48 (August), 243-248 and Unrelated Living Kidney Donors, An Update of Attitudes and Use Among U.S. Transplant Centers, *Transplantation*, 1994, 57(12), 1722-1726.

<sup>10</sup>Unrelated Living Kidney Donors, An Update of Attitudes and Use Among U.S. Transplant Centers, *Transplantation* Vol 57, 1722-1726, No 12 June 1994 at 1722-1726.

<sup>11</sup>Ibid at 1723.



#### **10.2.3.5. Voluntariness / Pressure.**

Respondents answered the question "How do you identify prospective donors?" More than one answer was often given. 72% stated that the patient approaches the family, 39% stating that the spouse or parent of the patient approaches the potential donor, 12% stating that the transplant co-ordinator approaches the donor and 46% stating that nephrology staff approach the donor. The EUROTOLD findings appear to suggest that around one half of centres with an LDT programme proactively use staff to approach potential donors. This is a similar picture to that found by the British Transplantation Society in its recent survey of U.K. transplant centres (15 out of 31 active in LDT took a proactive approach to potential donors).<sup>12</sup> There is an ethical dilemma about which approach to use; on the one hand a proactive approach is likely to be very effective and on the other it can give rise to situational pressure on the donor.<sup>13</sup> As we have seen, most centres do not routinely obtain a psychiatric/psychological evaluation of donors - surprisingly, given the concerns about motivation in donation.

#### **10.2.3.6. Financial Exchange Issues.**

##### **Compensation for Loss**

The centre questionnaire asked centres if they discussed the financial implications of donation with the donor and 42.86% of centres with an LDT programme do. Unfortunately, this question did not have the required specificity to ascribe clear meanings to the response. For instance, this could have been interpreted as meaning solely discussion of free medical treatment, or it could have been interpreted as such factors as discussing compensation for travel expenses, lost earnings, non-intrinsic harms resulting from donation, compensation for intrinsic harms and even actual profit from donation. 35.29% of centres with an LDT programme stated that financial help was available but it was again unclear how this question was interpreted and what help was available. One thing that is clear is that more than half of responding centres do not discuss these questions and in about two thirds of cases no financial help is available.

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<sup>12</sup>See P.S.Veitch, Recent Initiatives From the British Transplant Society in D.Price and H.Akveld, Living Organ Donation in the Nineties: European Medico-Legal Perspectives, *EUROTOLD*, 1996, 19-23.

<sup>13</sup>For a further discussion of issues in this area see chapter 6.



This is a matter of serious concern based on the fact that studies indicate that a significant minority of donors undergo financial hardship through donation.<sup>14</sup>

### Profit making.

There were no questions on this area within the Centre Questionnaire but the Attitudes Questionnaire had one question (No. 2) which could be related to profit making which stated that:

"A 50 year old Asian man with diabetic renal failure has been on dialysis for 5 years and is starting to get retinopathy. He has not been offered a cadaver kidney. He has no suitable or willing donors in his immediate family. He wants to go to India to have a kidney from an unrelated donor"

The responses from the 3 choices were as follows; let him go 24%, offer him a blood group compatible cadaver kidney 24% and leave him on the waiting list 55%.

It is difficult to deduce support or otherwise for commercially oriented transplantation from these answers. Firstly, it is not definite that the kidney in India would be supplied on a commercial basis, although this is probable. Secondly, the 24% letting him go may have responded in this fashion simply because they might not have much control in the matter. Perhaps the most interesting result is that 24% of respondents would be swayed into upsetting principles of distributive justice in the waiting list by offering him a blood group compatible kidney. It would appear that some transplant professionals are susceptible to letting the fear of commercial donation influence the fairness of their decisions.

### 10.3. Conclusion.

The attitudes of transplant professionals are a key in determining whether use of LDT will be expanded and if so in what ways. European attitudes suggest that an expansion of use is likely to occur. However, as well as the practical obstacles to overcome, there are several attitudinal factors which must be addressed if expansion of LDT is to occur within reasonable ethical limits.

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<sup>14</sup>See chapter 8.3.



More must be learnt about the reasoning for antipathy towards living donation, in general or specific forms of it, amongst some centres. Centres with an existing LDT programme have, on average, the most liberal attitudes towards LDT and will probably deliver a lot of the initial increases in its use. However, addressing the organ shortage may also require 'bringing to the light of day,' through further attitudinal research, why some centres are choosing to not use LDT or use it rarely.

It may already be theorised that irrational attitudes are having a restrictive impact on LDT use - for instance many practitioners will consider first degree relatives as living donors but not spouses or sons and daughters. Additionally, most professionals would apparently reject out of hand a 14 year old twin as a living donor.

Inevitably, liberal attitudes often take time to filter through into practice. It is likely that the main expansion will come through increases in more conventional forms of LDT like sibling and parent-child donation. There also appears to be scope for increase in spousal donation. Although positive towards LDT, EUROTOLD's results are nowhere near as enthusiastic as results of Spital's 1994 US study. This study found that over half of the responding centers prefer living related donation to cadaveric, while only 8% took the reverse view,

..."while a 1985 survey revealed that 54% of responding U.S. transplant centers preferred living related donors just two years later that number had fallen to only 36%. Now the present data show that over the past six years this previous downward trend in the popularity of living donors has reversed.." <sup>15</sup>

Spital suggests that the basis of these changes is as follows,

"Besides its obvious potential to mitigate the organ shortage, other considerations supporting unrelated living kidney donation may be summarised as follows: (1) the risk to a healthy living donor is very low and is independent of the relationship to the recipient; (2) the more distant the relationship of the donor to the recipient, the less likely there is to be psychological coercion, and the more likely the altruistic donor is to be a true volunteer; (3) the fear that unrelated donors harbour psychopathology has been disproven

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<sup>15</sup>Ibid at 1725.



by studies demonstrating that altruism is generally what motivates these remarkable people to give; (4) in other areas of life, taking risks to help people is generally considered heroic, not crazy; (5) motivation should not even be an issue when the donor is closely related to the recipient emotionally; (6) like having related donors, many unrelated donors benefit psychologically from donating through meaningful and persistent increases in self-esteem; and (7) surveys of the public have shown that the great majority are willing to donate to their spouses and most believe that donations by friends and even strangers should be permitted."<sup>16</sup>

While these are clear arguments for looking on living donation favourably most of them do not really explain the sea-change of attitudes in the US in the last 6 years. Most if not all of these factors were known well before the 1990's - for instance many of the studies done with donors and recipients were done in the 1970's, as noted in the previous chapter. These points have tended to be confirmed with time but probably the single most reason for the changes in attitude has been the fact that waiting lists have been increasing in size and has become increasingly unrealistic to suppose demand will ever be met by cadaveric supply in practice even if this goal could be obtained in theory.

The research in this chapter points toward there being significant scope for further development of protocols and guidelines for use of living donation. Such development should help to facilitate greater use by providing a clear framework for practice. It may be hypothesised that the fact that the majority of centres have not got written guidelines has mitigated significantly against their expansive use of LDT. In particular, the absence of clear written guidance is likely to deter practitioners from using forms of LDT perceived as more ethically marginal, such as spousal donation and use of minors and may explain why practice is nowhere near as liberal as attitudes. In addition, guidelines would bring benefits in terms of explicating a clear method of 'approaching' the subject of LDT with prospective donors. The advocacy of a proactive or reactive approach can be made, as well as wider consideration of how the process leading up to the act of donation might be best designed so as to ensure informedness and voluntariness in the process. More research is needed in this area but there would also be no harm in centres acting now to develop clear written guidelines. In addition, there appears also to be a role for developing laws and national guidelines; most importantly to address some of the

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<sup>16</sup>Ibid at 1725.



misconceptions that exist about the basic legality of LDT and improve understanding about the conditions under which it is legally acceptable for living donation to take place.

Most centres do not have a clear policy on issues of financial exchange. The process of compensating donors for losses is not just piecemeal because of the regulatory position in many countries but also because the issues are not always discussed (in fact they were discussed in less than half of the centres responding) and help is not standardly available (it was available in only half of the responding centres). More study of attitudes towards levels of financial exchange is required, in addition to more consideration of the issues by clinicians.

Finally, further research is needed to decipher the relationship between law and practice. However, as a matter of common sense it is clear that regulation will have some impact on this practice. To this end, regulation must be designed to facilitate LDT as much as possible within the context of an ethically sound framework. It is immediately apparent that facilitation could include:

- offering relief to practitioners at the centre level from making decisions on more ethically marginal forms of LDT (perhaps providing the option to go delegate the decision or take recommendation from an authority set up under law);
- making regulation comprehensive but at as simple as possible, backed by guidance and education; *and*
- encouraging cross-fertilisation of knowledge of laws between countries (such as facilitated by LEGISEARCH, the work of WHO and this research) and where appropriate the development of detailed legal models and harmonisation.



## **Chapter 11 Conclusion.**

### **11.1. Introduction.**

With only a few countries being able to keep up with the increasing demand for organs through bolstered use on uncontroversial methods of cadaveric procurement, the field of transplantation is at a cross-roads; continue on the well trodden path of limited LDT use *or* adopt a more adventurous approach and gain the quality of life and economic rewards that can come from much higher rates of transplantation. Legislators and transplant professionals must draw firm conclusions as to the legitimate use of LDT rather than drift along a line unconsciously set by conformity, over association of LDT with the organ trade or the 1980's dawn of (generally) false hope for CDT sufficiency. The conclusions of LDT studies like EUROTOLD and this PhD come at a most opportune moment to assist a swift resolution of the ethical and public policy factors fashioning the contemporary role of LDT and equally speedy action to re-align regulatory frameworks with these factors is critical for procurement.

### **11.2. General Justifications for LDT according to Philosophical Theories and Principles of Bio-medical Ethics.**

The general legitimacy, or otherwise, of LDT is basically a matter of applied ethics; requiring a rational synthesis of philosophical theories and the 4 principles of bioethics.

An extreme form of utilitarianism would ignore donor autonomy and aim simply at the most beneficent outcome in organ transplantation. This would no doubt be the elimination of waiting lists using the best donors (i.e. those likely to suffer the least harm and generate the highest benefits for recipients). Under this regime cadaveric bodies would be automatically mandated for prospective utilisation in transplantation according to clinical criteria. Living donation would be a rare supplemental activity. This approach is unacceptable because it sublimates individual autonomy to a practice which many do not even agree with and ignores the widely accepted belief that



collective human development rests very much on respect for the sanctity of individual decision-making in so far as this is compatible with the rights of others and common-sense protection of the vulnerable. It can be concluded, in living donation and elsewhere, that: utilitarianism limits itself because the most useful approach is one that respects rights; *or* that utility must be conditioned by the philosophy of rights and principle of autonomy.

In the context of the 4 principles it is not reasonable to treat maleficence as an absolute principle preventing living donation especially given that most allopathic treatments cause harm (side effects) which are only justified by reference to overriding benefits. The problem is that while in the overall assessment donations have the potential to advance justice, beneficence and autonomy<sup>1</sup> they can generally only be justified for the donor as an exercise of autonomy. The empirical research (including that conducted for this research) and general psychological literature have highlighted the problems there are in trying to show, on psychological grounds, that being a living donor is beneficent or prevents maleficent psychological consequences. Indeed, this is a key reason for the unease shown towards the idea of donation by an incompetent.

The starting point of bioethics and law has always been to presume that autonomy is a legitimate basis for action. The significance of autonomy in living organ donation will of course vary according to the circumstances. There is less reason to restrain a donor's autonomy where the 'balance sheet' of donor and recipient benefit and detriment is 'in the black.' However, concern to protect all prospective donors arises because the decision-making context is rarely neutral (structures, personnel and processes of transplantation are typically aimed at eliciting a yes-to-donation response) and decisions typically immediate and impulsive - possibly in some cases reinforced by unconscious distortions (e.g. strong underestimation of risks) more than rationale.

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<sup>1</sup>Ethical Aspects of Different Types of Living Donation, in Price and Akveld (ed), Living Organ Donation in the Nineties: European Medico-Legal Perspectives, *EUROTOLD*, 1996, 40-48 at 40.



Another area where autonomy might be restricted is on the basis of the rights of others. The public and those involved in transplant organisation have a right to expect protection of the wider beneficent reputation of the medical enterprise and the ethical and economic value of transplant activities. Endorsement of living donation may properly be restricted to instances where prospective detriment is both limited and *heavily* outweighed by prospective benefit. This will help to ensure that LDT's conducted are transparently and very significantly beneficent, and a consequent efficient use of resources, endorsement of the reputation of the profession and, for the overriding majority of practitioners, identifiable as potentially ethical and valuable to engage in. This approach still offers plenty of leeway for using living donations as a major kidney procurement source, significant leeway in liver segment transplantation and a limited leeway in the case of some other organs or at least their parts (e.g. lung segment).

Upon the above principles, and with the proper utilisation of cadaveric donation, each organ procurement area has the capacity to develop a strategy of reducing waiting lists/times, eventually to an insignificant level. Many countries would need to fairly extensively use living donation simply to bring the waiting list down to the level where less than one-year waiting times were the norm.<sup>2</sup> Even with transplant need on the increase, the goal of low waiting lists should be achievable for nearly all countries instituting a good cadaveric programme in combination with rates of LDT still considerably below Norway's.<sup>3</sup> Exceptions are countries which continue to have powerful cultural and attitudinal obstacles to 'normal' methods and levels of cadaveric procurement.<sup>4</sup>

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<sup>2</sup>Conversely, one or two other countries wouldn't need to adopt this approach e.g. in Eire the waiting time for a kidney transplant is generally less than one year and LDT is rarely used

<sup>3</sup>Graph 14 (end of chapter 3) illustrates that many Western Countries would have reduced waiting lists by 25% over the period 1990-1994 by having a level of LDT less than 15 p.m.p. For further statistical details see chapter 3, including the graphs at the end of it.

<sup>4</sup>E.g. Japan, Poland.



### **11.3. Recommendations For A Rational Regulatory Framework For LDT.**

While emphasising the role of law in transplantation Casabona has suggested that,

"control by professionals, preventative control by health authorities and public education on ethical attitudes concerning organ donation, among other measures, are also very important."<sup>5</sup>

Clearly a package of provision is required for transplantation, and specifically LDT. LDT needs more comprehensive legislation than an average medical procedure due to being an area where there is a vulnerable party (the donor) and general ethical complexity and debate (fuelled by ongoing developments). As Price concludes,

"(t)he absence of legislation concerning LDT creates uncertainty, variability of practice, and an absence of transparency."<sup>6</sup>

General principles of law do not evolve quickly enough to fulfil the main function of law in transplantation; to establish clear minimum principles and conditions for the acceptable conditions under which living donors can be utilised. Unfortunately, existing transplant legislation does not comprehensively deal with all the significant LDT issues in a straightforward and clear manner, understandable to practitioners; as a result it may be generating wariness of innovation amongst practitioners, the majority of which are doubtless already cautious about moving beyond the norm of low LDT use.

Having a single, comprehensive transplantation law in each jurisdiction is clearly the goal. Nevertheless, because legislation takes time to change, it may need supplementing with a layer of regulation amenable to speedy alteration such as

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<sup>5</sup>Legal Issues Concerning the Living Donor and Some Criteria for Harmonized Legislation, in D.Price and H.Akveld (eds), *Living Organ Donation in the Nineties: European Medico-Legal Perspectives*, *EUROTOLD*, 1996, 139-155 at 139.

<sup>6</sup>The Texture and Content of Living Donor Transplant Laws and Policies, *Trans Proc* 1996, 28(1), 378-379 at 379.



statutory instruments and/or use of a legislative authority (such as ULTRA in the UK). While the structure within which LDT takes places should be nationally - and to some extent internationally - determined, centres, areas and individual practitioners should be encouraged to develop protocols for use and must retain the right to further restrict or even prevent living donation in their area (without preventing prospective LDT participants from seeking their opportunity elsewhere).

#### **11.4. Summation of Ethical Issues in and Proper Regulation of Specific Aspects of LDT.**

##### **11.4.1. Regulation of the Context in Which LDT May be Considered as an Option.**

Legislation has often been used to demarcate the context in which LDT may be considered as an option. A basic legislative framework here could be as follows:

1. LDT, in the circumstances of each case, must be the *optimum remedium* as regards the combined interests of the donor and recipient. In considering the *optimum remedium* practitioners should have regard to his/her centres average standard of cadaveric organs and average level of wait for a cadaveric organ in excess of the time that would be required for LDT to occur. LDT must be a significantly more beneficial clinical outcome for the recipient<sup>7</sup> than the average CDT in order to justify donor detriment.. Procedures with higher levels of prospective detriment than a standard kidney LDT<sup>8</sup> must be justified by exceptional need.
2. Where a prospective recipient is toward the front of the waiting list for a cadaveric organ, or otherwise likely to receive one shortly, only exceptional circumstances can justify use of LDT. Exceptional circumstances might include: Exceptional recipient need; and a prospective donor, neutrally presented with the fact that

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<sup>7</sup>E.g. because of high quality match or high recipient need.

<sup>8</sup>E.g. liver segment, lung lobe.



donation can be of value both to the prospective recipient and to the wider community of persons waiting for a transplant, unsolicitedly volunteers to donate.<sup>9</sup>

Regulations or Codes of practice may periodically give concrete guidance on such matters as health and safety standards, minimum levels of organ compatibility and practical advice on how to balance detriment and benefit in the light of current practice.

#### **11.4.2. Limits to Donor Detriment**

The key ethical purpose of regulation in this area is to limit the level of prospective detriment posed to the prospective donors health and ensure they are significantly exceeded by prospective recipient benefits. Accordingly legislation should determine that:

1. Safety checks for the donor must reflect a reasonable assessment of best world-wide practice;<sup>10</sup>
2. The likelihood of death for the donor must not significantly exceed the likelihood of death from being placed under general anaesthetic;
3. Expected detriment to the donor must be low including, minimal likelihood of serious injury (The extreme rarity of mortality from kidney donation and the apparently low levels of short and long-term risks<sup>11</sup> means it would meet this criteria under normal circumstances as would some other forms of living donation like liver segment or lung lobe. Living donor pancreas vessel donation might be ruled out altogether.<sup>12</sup> Alternatively, the prospective detriment of such a procedure might limit its use to circumstances where it is the only and life saving alternative with reasonable likelihood of success);

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<sup>9</sup>This provision is essentially designed to make sure that it is the donor knows and consents to the exact purposes of his/her donation and is not unknowingly led into a donation that is justified almost solely according to its prospective benefit for the collective body of prospective recipients when thinking that in fact the donation is very much chosen as being optimal the optimal choice for their situation as individuals.

<sup>10</sup>This would result in the exclusion of donation at centres or in countries not being able to afford the necessary equipment (e.g. Romania) or cutting corners to derive greater profit (see chapter 8).

<sup>11</sup>See chapter 3.4.2.

<sup>12</sup>For discussion of the risks see chapter 3.4.2.



4. Authorising professionals must weigh up expected and possible detriments and only proceed where these pose a limited threat to the prospective donor which is significantly exceeded by prospective benefit to the recipient (this involves legislative embodiment of a more or less standardly applied ethical principle, one which still leaves plenty of practical scope for living donation but at the same time acts as a safety net against LDT's of dubious or marginal value).

A regulatory body set up by statute (as with HOTA in the UK) could determine a list of organs which could be considered for donation, be called upon by practitioners to give guidance in any individual case and determine the acceptability or otherwise of new forms of procedure. Such a body, or again a professional body, could give specific guidance for different types of organ LDT as a whole.

The above principles treat the principle of non-maleficence as paramount where prospective detriment is above a certain level.<sup>13</sup> At the same time as setting firm limits they allow the justifiable exercise of donor autonomy in taking small consequences and risks of harm for the anticipated significant benefit of others. Clearly where the donor is unable to consent the level of acceptable maleficence could be further restricted and/or the required beneficence increased. Suggested regulation of donation by persons unable to consent is examined at 11.4.5.

### **11.4.3. Procedural Requirements**

1. Donors must evidence their informed, voluntary and non-profit motivated consent by signing a form stating that the donation is a voluntary not-for-profit act done with knowledge of the major possible and inevitable consequences in accordance with their true will *or* by a method of equal veracity where following method is not practicable.<sup>14</sup>

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<sup>13</sup>A most obvious example would be corneal donation where not incidental to a clinically therapeutic removal for the donor. This point has been brought sharply into focus by the fact that one of the Leicester donors wants to give his remaining kidney to a second son with end stage renal failure. Such a procedure would probably be illegal and unlawful under the common law - see further chapter 6.

<sup>14</sup>E.g. due to a certain disability.



2. Recipients must evidence their informed voluntary consent by signing a form (or an equally veracious method) stating that the organ LDT reflects their true will and they have knowledge of the major possible and inevitable consequences for themselves and the donor.
3. A duration of at least 48 hours (or exceptionally 24 hours) must have elapsed between agreement and removal.
4. Professionals giving information to, or asking for consent of, the prospective donor shall not be the same people as the professional involved in caring for the prospective recipient.

The above provisions are not intended to be an exhaustive list for all situations. For instance, additional requirements could be imposed where necessary to ensure the informed, voluntary and non-profit motivated consent of prospective donors or classes of donor in a jurisdiction with a history of organ trade, or simply to ensure bona-fide motive for donation with certain classes of donor in all jurisdictions and to protect vulnerable prospective donors such as those unable to give consent for themselves.

#### **11.4.4. Professional-participant communication**

Professional communication to the donor is a critical area. Not just the neutrality of information, which relates to the issue of voluntariness discussed later, but also the general extent of communication and the process of verifying that the communication has been successful.

1. Professionals shall make all reasonable attempts to inform prospective donor and recipient of the clinical risks and benefits of the procedure for both parties. The information shall be given in broad terms but also highlight specific areas of significance such as the main normal physical and psychological consequences, risks of serious injury or death and risks of detriments significant in nature and/or likelihood of occurrence. Regulations passed under legislation may



from time to time specify the types of risks that would need disclosure under this provision in relation to the different forms of organ LDT.

2. Professionals shall make all reasonable attempts to inform the prospective donor of other matters relating to the LDT process that are likely to be significant to the prospective donor in their own right or as part of the decision-making process. This must include information as to how to claim financial compensation for donation and the likely financial implications of donation having regard to the compensation available and the situation of the specific prospective donor. It may also include information relating to the possible social and psychological impact of donation on the donor having regard to studies in this area and the donors specific situation and motivations for donating.
3. The package of information offered and the methods for it's communication (e.g. audio visual, tape recorded, multi-media, signed, paper-written and spoken) must reflect a reasonable attempt to address, the needs, abilities and disabilities of the prospective donor and recipient, bearing in mind the ideal result of the donor understanding all the significant factors involved in the process. The information may also be from different sources - such as different professionals within the centre, former LDT donors and recipients and literature.
4. LDT can only be conducted subject to both donor and recipient evidencing a comprehension of the significance of their decision.<sup>15</sup> To this end all donors and recipients must be properly informed irrespective of their wishes.

Informedness in LDT is treated with great seriousness in the above provisions. This is entirely reasonable given the importance of good decision-making as a justification for LDT and the context of empirical and theoretical concerns about disclosure and the basis upon which decisions are made. As regards donor decisions, evidence from previous studies and this research indicates that donors typically make apparently impulsive decisions to donate and in some case exhibit unconscious motivations (post-decision distortion of reality in the direction of favouring donation

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<sup>15</sup>Regulations passed under the legislation are to set out best practice in this area such as post-communication getting the donor and recipient to write a statement as to their understanding of the major prospective consequences of the LDT for both parties. Further communication could then take place where there were significant gaps in understanding.



in order to avoid uncomfortable feelings e.g. about risks, possibility of using another donor etc.) and sometimes shut off from a discussion of risks etc. That is simply not good enough where they are engaging in a procedure which is against their physiological interests. The recipient has been given special consideration because his/her peculiar interdependence with the donor warrants it; it is one thing to not fully understand what one is getting oneself into but *where* one is getting *another involved* as well there is an *ethical duty* for you *to be informed*, to *know* what is involved in detail *and* to *make a reasoned assessment* as to whether involving that other person is legitimate in the circumstances. The doubts concerning donor decision-making processes serve to amplify this duty (i.e. by making it more critical that the recipient makes a decision about the value and ethics of the donation and whether it is justified in the circumstances to receive from the prospective donor).

To prevent practitioners from being deterred, regulations pursuant to legislation should closely detail what is required to comply with the legislation. An authority set up under law could advise transplant centres on compliance with the criteria.. The donor and recipient can take action in most jurisdictions only in cases of negligence and battery. A scheme of no fault liability should be instituted in this area, if not more generally.<sup>16</sup>

#### **11.4.5. Use of Donors Without Full Capacity**

All cases involving incompetents persons shall be referred for to an authority set up under the legislation which shall determine which donations shall go ahead according to the principles below (practitioners may also refer to this authority for a determination of whether a person has capacity in borderline cases):

1. The consent (or otherwise) to donation of competent minors and adults who have a mental illness or disability, but are nethertheless competent, shall be determinative of whether donation takes places, irrespective of the wishes of

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<sup>16</sup>In addition donors and recipients might have some grounds to complain under a Citizens Charter type format where practitioner standards meet legal requirements but are still below par. A nominal compensation of donor and recipient might also be acceptable here.



parents and subject only to the normal rules relating to donation applying to competent adults who have no mental illness or disability;<sup>17</sup>

2. In order to become organ donors, incompetent persons should at least give meaningful agreement to donation, there must be special justifications for the procedure and the relevant legal consent(s) must be given in accordance with general principles of law.
3. The incompetent's assent and lack of objection to donation shall be sufficient where there is a high probability that (s)he will endure low detriment from donation *and* suffer serious detriment from not donating due to the nature of his/her relationship with the prospective recipient and the donation being the only viable course of action to avoid serious danger to the life or health of the recipient.

The general need for meaningful agreement by incompetents helps to ensure that the donation is a meaningful exercise of autonomy whilst preventing donation by persons with *no significant* comprehension of how to weigh the procedure and its consequences is in some regards protecting them. A tight exception to this is created where the donation is more assuredly in the prospective incapacitated donor's best interests as avoiding the high probability of serious detriment.

#### **11.4.6. Use of Different Classes of Donor in Terms of their Relationship with the Recipient.**

1. Prior to undertaking a donation the practitioner must ascertain the nature of the relationship between the donor and recipient.
2. Where genetic relationship is claimed a scientific screening test shall be utilised to test the accuracy of the claim.
3. Where the relationship claimed is of a non-genetic familial nature, clear evidence of a long term significant relationship and non-commercial motivations (e.g. altruism, family solidarity) for donation shall be required. Where such

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<sup>17</sup>As already seen in chapter 7, some laws prohibit minors from donating altogether whether or not they have capacity and prohibit donation by competent people who have a mental disability or illness.



evidence is lacking (as it might be in the case of some friends) the prospective donation must be referred for a determination by an authority set up under the legislation who shall closely investigate and analyse the motivations of the prospective donor and recipient.

The law that comes closest to meeting these objectives is Hong Kong's 1994 Ordinance.<sup>18</sup> This approach to regulation provides a framework within which doctors can have the legal certainty and practical support to take clear action which in turn may increase LDT use,<sup>19</sup> particularly spousal donation.<sup>20</sup>

While there is no *clinical* reason to discriminate between different classes of donor *per se* discrimination against certain classes does occur on *pragmatic* grounds of avoiding financially and psychopathologically motivated donation. The impracticalities of effectively policing motivation in stranger donations, combined with the likelihood of suspect motivation, warrants the exclusion of this class unless an anonymous method of giving can be established. However, excluding other classes of donor may be excessive and inconsistent given suspect motivation<sup>21</sup> probably exists as much in familial as in friendship donations.

#### **11.4.7. Voluntariness and Informedness of Donor Consent.**

1. Practitioners must make reasonable attempts to ascertain that the act of donation reflects the true will of the donor. To this end a psychological evaluation should be made, including evaluation of a short written statement by the donor of his/her main feelings about the donation and reasons for wanting to donate.

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<sup>18</sup>Which treats spouses of 3 or more years standing in the same way as close genetic relatives and through an authority set up for the purpose adopts a more rigorous analysis of motivation of other prospective donors who are not close genetic relatives of the recipient. Hong Kong's law is similar to HOTA 1989 as already observed in Chapters 6 and 7.

<sup>19</sup>This view has been stressed by Bob Pilling, Chair of ULTRA, in David Price's 1996 communication with them. In personal communication Ferenc Perner of the Budapest transplant centre has also expressed this view.

<sup>20</sup>An area attracting considerable interest which, with appropriate scrutiny is possible to conduct with relative certainty that commercial motivation is not present. Hong Kong's Ordinance is a possible model for regulation here in requiring the spousal relationship to be of three years standing or to otherwise be scrutinised for commercial motivation etc. by an Authority set up under the law.

<sup>21</sup>Albeit often of a different kind.



2. Practitioners must make reasonable attempts to ensure that the process leading up-to donation presents as neutral and unbiased a climate as possible for prospective donors to consider their decision.
3. The donor must be able to revoke the decision to donate (verbally, in writing or by any other method) at any point before the procedure commences (the same provision should exist for the recipient).

Clear centre protocols should be developed out of national guidelines. Such protocols should address issues that are central for the prospective donor in the process of decision-making, including: who makes the initial approach to the prospective donor (e.g. family, recipient, a medical professional); whether prospective donors are offered 'a way out without losing face' (e.g. professional stating that donation was not possible for medical reasons); where prospective donors will get information from as a matter of course and further sources of information they can seek out; at what point in the process are prospective donors asked to make a decision and by whom; *and* who will work with the donor exploring motivation (e.g. counsellor, psychiatrist, psychologist) and exploring donor misconceptions (e.g. distortion of level of prospective detriment).

One of the criticisms of living donation is that almost whichever way the donor is informed of the possibility of donation the fact of being informed itself creates a pressure to donate.<sup>22</sup> However, while not approaching people to donate and just waiting for them to volunteer is the safest approach, approaching the donor is reasonable if done with care.

#### **11.4.8. Limits to Financial Exchange.**

1. Profit making from organ donation by any parties shall be prohibited.
2. Acceptable payments are limited to: the normal salaries given to persons involved in the organisation and practice of transplantation at government

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<sup>22</sup>See C.Byk, Living Organ Donation European Perspectives, in Living Organ Donation in The Nineties: European Medico-Legal Perspectives, (ed Price and Akveld), *EUROTOLD*, 1996, 53-62.



- sanctioned hospitals; *and* the compensation of the donor for physical and financial losses reasonably incurred in the LDT process
3. Donor compensation of the kind described above is a right. Where the donor cannot get full compensation from other sources the state shall make up the shortfall, e.g. through a fund set up for the purpose. Losses covered shall include: those associated with time-off work (both for self-employed and employed); cost of convalescence care; childcare requirements; reasonable hotel / travel expenses under limits set out by the government; *and* reasonable compensation (under limits set out by government) of normal and unusual harms arising from the donation process.
  4. Legislation shall require employers and financial organisations to pay compensation for, respectively, prejudicial treatment of the donor in the workplace and obtaining life insurance.
  5. Legislation may on an experimental basis provide the donor with a reasonable but basic payment reflecting the amount of time and effort expended that has not been otherwise compensated for in the above provisions. The impact of this approach on factors like organ quality and levels or procurement shall be monitored closely by each transplant centre who shall relay this information on a regular basis to an authority set up under the legislation. The authority will monitor the national picture and make recommendations for legislative changes where appropriate.

The above approach both ensures that donors suffer no economic detriment from the act of donation and allows policy-makers to dip a toe into the realm beyond voluntary exchange but still restricted within a non-profit making framework. The idea of allowing a basic payment would put donors in a somewhat similar position to some medical research volunteers.

### **11.5. Critical Analysis and Areas for Future Research**

At the beginning of this research it was clear that LDT needed serious consideration as a method of reducing organ shortage. Xenotransplantation has developed rapidly



during the 1990's but its usage as an organ procurement will not become a reality in the short term. The need to facilitate greater use of organ LDT is urgent. To this end regulation must help to bridge the gap between professional attitudes and practice creating a framework where practitioners have: More scope to use LDT; more certainty as to what the constraints are; *and* more unequivocal support from policy makers for the principle of extensive use of LDT. Poor draftsmanship, or lack of consideration of the issues, has resulted in elements of legislative vagueness, irrationality, restrictiveness and coverage limited to a particular area of LDT (such as financial exchange). International bodies must encourage the creation of ethically assured but facilitative regulatory frameworks for LDT and *cease* discounting LDT as a major source of organs; it is hoped that investigations like EUROTOLD and this PhD encourage the sea change in approach which may be beginning in Europe through the Council of Europe's 1997 Draft Protocol on Organ Transplantation<sup>23</sup> and will hopefully be reflected in the current review of the WHO Guiding Principles on transplantation.

Of the suggestions for regulation in different areas of LDT examined in the previous section of this chapter, one feature stands out; the continual re-appearance of the recommendation of use of a legislative authority set up under law. Such an authority is effectively being suggested both as a quasi-judicial body (determining issues like whether to allow prospective donors without capacity or friends or strangers to donate) and also in a wider capacity of promoting and checking standards of practice in LDT. The use of such an authority will ensure the most difficult ethical issues for practitioners are independently examined. A practitioner faced with an option that is toward the margin of normal practice may be encouraged to consider it if the difficult considerations of ethics and law are examined by a competent outside body that is in no way as formal as a court. The authority itself may feel more unconstrained to take a bold interpretation of the regulations - as occurred for instance in the recent acceptance of a lung lobe LDT between friends by ULTRA.<sup>24</sup> At the same time practitioners would still, of course, be at liberty to reject the possibility of doing

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<sup>23</sup>Steering Committee on Bioethics (CDBI) Strasbourg, 11 February 1997. Likely to be 'declassified' soon.

<sup>24</sup>David Price interview with Bob Pilling, chair of ULTRA.



organ LDT (in particular cases or in general) where this was inconsistent with their policy. At a time when use of more marginal forms LDT (both LDT of non-renal organs and more marginal renal donations) is increasingly being considered, the expertise such an authority would build up in dealing with complex ethical and legal issues would be vital.

A final interesting feature of regulation to point out is the large number of legislative provisions suggested in the previous section of this chapter. As Price has noted, there has been a trend in transplant legislation away from a small number of provisions towards a framework that is "very detailed and comprehensive."<sup>25</sup> This trend is borne out of the increasing body of ethical issues that have arisen in practice and the sophistication with which ethical issues are in general now viewed. However, even the most recent attempts at legislation still have a long way to go. The logical way forward may include bringing policy makers together for increased efforts at harmonisation of legislation under the auspices of the EC in Europe and influenced by the WHO on a world-wide basis. Now is also a good time for the UK specifically to resolve its legislative inadequacies and in particular its simple over reliance on the common law.

Increasing organ shortages also demand that practitioners urgently re-examine the reality of the negative consequences of non-extensive LDT use. Investigations such as EUROTOLD and this PhD along with wider exposure of the issues at international transplant meetings can play an important role in highlighting through statistics, economics and quality of life arguments that living donation must be considered seriously as a mainstream procurement modality.

As well as action, there are specific areas in LDT that need further multi-disciplinary investigation:

*Firstly*, non-renal forms of LDT are relatively new; parallel with ongoing use of such LDT's there must be a detailed empirical analysis - not only of data pertaining to

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<sup>25</sup>Questioning Attitudes to Living Donor Transplantation, *EUROTOLD Project Management Group Final Report*, ch2 at p36 (Ed EUROTOLD PMG with this part written by D.Price).



detriment and benefit but also participant and practitioner attitudes and experience. This will help an ongoing evaluation of the ethics of non-renal forms of donation and their appropriate regulatory framework;

*Secondly*, there must be ongoing monitoring and practical and ethical evaluation of xenotransplantation.

*Thirdly*, along with new regulatory provision being put in place, there needs to be ongoing empirical study of processes of informing participants, levels of participant understanding and reasoned decision-making and motivations, pressures and voluntariness in donations. This is not merely to provide evidence for the ongoing justification or otherwise of LDT but also to enable periodic refining of regulation in alignment with what the ethical concerns are in practice.

*Fourthly*, ongoing European, indeed world-wide, study of practitioner attitudes is another important feature. Such study will involve periodic survey and analysis of centre and practitioner practices and attitudes, addressing misconceptions and specific concerns in modifications to regulation where appropriate.

Finally, one of the main criticisms of this research is a reiteration and elucidation of the comments in chapter 1 on the limitations of utilising the medical model in response to organ disease. Problems of scarcity are common to conventional medicine; in transplantation both scarcity of financial resources and scarcity of organs exist. Scarcity, and with it the maleficence of side effects in organ transplantation, risks and consequences to living donors and potential pressures on the donor, could be avoided through the utilisation of a successful holistic approach to prevention and neutralisation of organ disease. The irony of holding fast to the current system calls to mind a Danish Gruk;

"we shall have to evolve problem solvers galore  
since each problem they solve  
creates 10 problems more."<sup>26</sup>

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<sup>26</sup>Piet Hein, quoted from Linda Neilson's paper: Living Organ Donors: Legal Perspectives From Western Europe in D.Price and H.Akvelld (ed.), Living Organ Donation in the Nineties: European Medico-Legal Perspectives, *EUROTOLD*, 1996, 58-71.



Although public interest in holistic medicine is increasing its role is still largely minimised in the medical mainstream. In most countries holistic medicine has not been seriously and systematically considered within the context of organ disease despite the fact that many forms of holistic medicine have been established for thousands of years (e.g. herbalism) and even now are the 'conventional' system for medicine in a significant proportion of the world (perhaps most notably China and many other areas of the 'East'). A large scale comparative study of holistic and mainstream methods could present a valuable area for future research.



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## **Appendix 1: Associated Scholastic Activity.**

### **1A: Papers and Reviews Given**

1. Review of 'Organ and Tissue Transplantation in the European Union: Management of Health Difficulties and Health Risks Linked to Donors (ed. Dr Yvon Englert, Martinus Nijhoff, 1995) published in the World Health Organization's International Digest of Health Legislation, 1996.
2. To Pay or Not to Pay That is the Question: The Economic Rights of the Living Donor (In D.Price and H.Akveld (ed) Living Organ Donation In the Nineties: European Medico-Legal Perspectives, EUROTOLD, 1996: 166-173).
3. EUROTOLD statistical database. Presented at the Rotterdam Symposium November 1995.
4. Review of Commerce and Compensation Provision in European Legislation Related to Living Organ Donation 1996. Compiled as part of LEGISEARCH (David Price and Austen Garwood-Gowers available on the Internet: <http://www.maths.ac.uk:2080/MedStats/Eurotold>).
5. Poster Presentation on Legal Aspects of Living Donation in Europe at the CITIC Conference On Organ Shortage: The Solutions, Lyon, June 1994

In addition I was second author to two of David Price's papers (Transplantation From Minors: Are Children Other People's Medicine? Contemporary Issues in Law, 1995, 1(1), 1-27 and The Texture and Content of Living Donor Transplant Laws and Policies, Transplantation Proceedings, 1996, 28(1), 378-379).

### **1B: Contacts Established During The Period of Research.**

Main contacts relevant to the Phd are discussed below. EUROTOLD had an extended number of contacts in addition to these including several hundred clinicians from centres across Europe that participated in answering the EUROTOLD questionnaires / filling donor health form responses for the EUROTOLD Donor Health Registry.

#### **1B(i): Methodology, Statistics, Questionnaires and Interviewing.**

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### **1B(ii): Ethical Aspects of Living Donation.**

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### **1B(iv): Legal Aspects of Living Donation.**

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### **1C: Conferences and Symposia Attended.**

1. Manchester Conference on Bioethics, November 1991, Centre For Ethics and Social Policy, Manchester University.
2. Rhodes, 6th ESOT Conference, October 1993.
3. Warsaw Symposium on Living Donation, March 1995, Organized by EUROTOLD and the Warsaw Medical School.
4. Rotterdam Experts Meeting on Legal and Ethical Aspects of Living Donation, November 7-8 1995, Organized by EUROTOLD and the Rotterdam Centre For Health Policy and Law.

### **1D: International Visits.**



1. Geneva, World Health Organization, 1992. Given access to WHO databases on transplant laws.
2. Oslo, Rikshospitalet, August 1992. Interviewing donors and recipients and various professionals concerned with transplantation.
3. Dublin, Beaumont Hospital, April 1993. Interviewing donors and recipients and various professionals concerned with transplantation.
4. Leicester, 1994, Visit of Hans Akveld and Frank de Charro (dutch EUROTOLD collaborators) to Leicester to meet members of the EUROTOLD Project and engage in wide ranging discussions relating to ethical and legal aspects of transplantation.
5. Leicester, October 1995 as above.
6. Frankfurt, December 1995. Meeting of PECO participants for discussion of living donation in Eastern Europe and the development of the PECO scientific programme.
7. Budapest, April 1996. As above.



## **Appendix 2: Donor and Recipient Interview Materials.**

### **Appendix 2A: Questionnaire Formats.**

**Figure 1: First draft for interviews with Living Donors**

1. What Organ did you donate, when and to whom? What is your relationship to the recipient?
2. Looking back, would you describe your impressions of the experience as a donor as essentially positive (favourable/good) or negative (bad)? What are the primary reasons for these positive/negative impressions?
3. Would you donate again if you could turn the clock back to a time just before the donation? Are you very glad you donated, not very glad you donated or not glad at all about it?
4. How did the question of you donating your organ first arise? Who first approached you about the matter? Were you given a direct invitation to donate or were you simply informed that the party concerned required an organ for transplant purposes?
5. When did you actually make a decision to donate? Was it an instantaneous decision or did you take time for reflection and consideration?
6. What was the main factor behind your decision to donate? Did you worry that you would feel guilty later if you did not donate? Did you feel a sense of family duty to donate?
7. Did you have any doubts or uncertainties about donating at the time? Would you have described yourself as very sure, fairly sure, rather uncertain or very uncertain?
8. Were you the only suitable candidate for donation? If not why were you the one who eventually ended up donating? Did you consider yourself to be the most appropriate donor at the time?
9. Was any actual pressure exerted on you by family members to donate? If so, was this direct pressure? What form did it take? Did you feel any pressure to donate quite apart from any pressure being deliberately applied to you?
10. What was your relationship with the family as a whole like at the time of donation? Was there any previous event in your life which attracted widespread disapproval?
11. Was any pressure to donate exerted on you by either the recipient or the medical team?



**Figure 2: First draft for interviews with organ recipients**

1. What organ did you receive, when and from whom (name and relationship)?
2. What was your likely prognosis without the transplant?
3. Was your transplant a success?
4. How has your mental and physical health been since the date of the transplant?
5. Looking back, are your feelings about the donation essentially positive or negative?
6. How would you describe your relationship with the donor prior to the donation? How has your relationship with the donor developed/changed since the date of the transplant?
7. Did you play any part in the selection of the donor or approach the donor about a potential donation?
8. Do you feel any guilt that you cannot fully repay your debt to the donor? Do you think that the donor expects more gratitude than you can give?
9. Were there any cultural or religious difficulties in the path of your receiving the donated organ?
10. How do you feel about your communication with the medical team? Did you experience any difficulties of communication with them? Were there any very good points about your relationship with the medical staff?
11. Do you feel you were fully aware of the nature of the procedure and the risks and benefits attaching to it, at the time of the transplant procedure? What additional information would you like to have been given?
12. Do you consider that donations of organs to persons who are only distantly related to the recipient, or only emotionally related to him/her e.g. spouses, cohabiting partners, friends etc. are acceptable?
13. Is the practice of buying and selling organs for transplantation acceptable in any circumstances?
14. What is your name, age and occupation?



**Figure 3: Approach to interviews with donors in the Eire study**

*Communication and Information*

We would like to understand how you feel about the information and communication within the process.

Specifically:-

where did you get information and understanding about the process of donation from?

what was your understanding of the risks and benefits of donation? (as much detail as possible)

how well did you feel you understood the risks and benefits involved? (prompt specific short and long term risks, minor/major).

how well were your needs for information and communication satisfied?

were there things that you would have liked to have known more about?

how you felt about the quality of support and care from your family and the medical staff?

*Exploration of the cadaver alternative*

We are wondering about the process by which living donation was decided upon in preference to cadaver

*Exploration of alternative donors*

We are wondering about the process that led up to you, specifically, being a donor

Who are the other people in the recipients family?

were all of them treated as potential donors? If not we would like to understand how a lesser range of people were drawn up.

how did the process take its course to exclude other possibilities?

*The process for donating*

We would like to understand the process that led you to donate a kidney and your feelings within this process

how did you first become aware that the recipient needed a transplant?

did you offer without being asked or did someone ask you?

when did you make your decision? straightaway? after talking with family and medical staff? after tests? did you ever reconsider?

what were your concerns (if any) about being a donor?

*Motivation and freedom in the decision*

Did you feel you could freely get out of the decision if you wanted to?

we'd like to understand if you felt anyone was pushing their opinions on you about donation?

if yes did this make a difference to the way you decided?

we'd like to understand the meaning that the donation had for you, can you describe how you felt about being a donor?

was it something you felt pressure inside yourself to do or did you feel free inside yourself about it?

If you could turn the clock back with what you know now do you think you would reach the same decision?

*Relationships*

We'd like to understand the impact the donation had on your relationships with the recipient and with other family members.

we are wondering if through the process these relationships were enhanced or otherwise and whether the process contributed to family conflict or not.

*Financial*

We would like to understand the impact the donation had in terms of money and matters like life insurance.

did you feel that you were fully compensated for any losses or could the hospital or some other agency have done more



**Figure 4: Approach in interviews with recipients in the Dublin study.**

*Communication and Information*

We would like to understand how you feel about the information and communication in the process  
 where did you get your understanding about the process of LDT from?  
 what did you understand about the risks and benefits of having a living donor?  
 how well did you feel you understood the risks and benefits?  
 how well were your needs for information and communication satisfied?  
 were there other things that you would have liked to have known about?  
 how you feel and felt about the quality of care and support from your family and from medical staff?

*Exploration of the cadaver alternative*

(As with donor - fig 3)

*Exploration of alternative donors*

(As with donor - fig 3)

*The process for donating*

not applicable

*Motivation and freedom in the donation*

What do you understand as the motivation for the donor to give you a kidney?  
 was it a decision that you felt you and/or the donor could freely get out of?  
 did you feel anyone pushed their opinions about donation on you or the donor or not?  
 is yes did this make a difference to either or both of you in the way you decided?  
 what meaning does the donation have for you?

*Relationships*

(As with donor - fig 3)



Figure 5&6: Final format donor and recipient questionnaires.

QUESTIONNAIRE: ORGAN RECIPIENT

for office

only  
Personal Details

Name \_\_\_\_\_ Male ☐ Female ☐

Address \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Date of Birth \_\_\_\_\_ Age \_\_\_\_\_ Religion \_\_\_\_\_

1. How many transplants have you had?

First:	Cadaveric	<input type="checkbox"/>	Living donor	<input type="checkbox"/>	Date: _____
Second:	Cadaveric	<input type="checkbox"/>	Living Donor	<input type="checkbox"/>	Date: _____
Third:	Cadaveric	<input type="checkbox"/>	Living Donor	<input type="checkbox"/>	Date: _____

Others: \_\_\_\_\_  
\_\_\_\_\_

2. What is your relationship with the living donor?

Father	<input type="checkbox"/>	Mother	<input type="checkbox"/>
Brother	<input type="checkbox"/>	Sister	<input type="checkbox"/>
Grandfather	<input type="checkbox"/>	Grandmother	<input type="checkbox"/>
Other	<input type="checkbox"/>	Please specify _____	

3. Do other family members have kidney problems?

No ☐ Yes ☐

If Yes, please specify \_\_\_\_\_  
\_\_\_\_\_

4. Was the living donor living with you at the time of the donation?

No ☐ Yes ☐

If Yes, who else was living at home? \_\_\_\_\_  
\_\_\_\_\_

If No, where was the donor living?  
\_\_\_\_\_  
\_\_\_\_\_

5. What was your marital status at the time of the transplant?

Married	<input type="checkbox"/>	Single	<input type="checkbox"/>
Cohabiting	<input type="checkbox"/>	Separated	<input type="checkbox"/>
Widowed	<input type="checkbox"/>	Divorced	<input type="checkbox"/>



6. Has this changed since the transplant?    No    ☐    Yes    ☐  
If Yes, how? \_\_\_\_\_  
\_\_\_\_\_

Finding a donor

7. When did you first become aware that you would need a transplant?

More than 5 years before reaching ESRF    ☐  
Between 1-5 years before reaching ESRF    ☐  
Less than 1 year before reaching ESRF    ☐

8. Did you have dialysis?    No    ☐    Yes    ☐

If Yes, what sort if dialysis?    First    Second    Third

Haemodialysis at home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Haemodialysis at dialysis centre	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Complete Ambulatory Peritoneal Dialysis (CAPD)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Haemofiltration <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

9. When did you start dialysis?    Month/Year \_\_\_\_\_

10. When were you placed on the kidney transplant waiting list?  
Month/Year \_\_\_\_\_

11. Was this before being on Dialysis?  
No    ☐    Yes    ☐

12. Were you ever suspended from the waiting list?  
No    ☐    Yes    ☐ If yes, why?  
\_\_\_\_\_  
\_\_\_\_\_

13. When did you first hear that it was possible to have a kidney from a living donor?  
\_\_\_\_\_  
\_\_\_\_\_

14. Who told you that it was possible to have a kidney from a living donor?

Kidney specialist	<input type="checkbox"/>	Family doctor	<input type="checkbox"/>
Transplant coordinator	<input type="checkbox"/>	Nursing staff	<input type="checkbox"/>
Another patient	<input type="checkbox"/>	A member of your family or friend	<input type="checkbox"/>
Other person who?	<input type="checkbox"/>	_____	



15. Did you ask someone to consider giving you a kidney?

Yes ☐ No ☐

If Yes, who did you ask? Mother ☐ Brother ☐  
Father ☐ Sister ☐  
Other ☐ who? \_\_\_\_\_

If No, did someone else ask?

No ☐ Yes ☐

If Yes, who asked? \_\_\_\_\_

Who did they ask? Mother ☐ Brother ☐  
Father ☐ Sister ☐  
Other ☐ who? \_\_\_\_\_

OR Did someone volunteer without being asked? if so who volunteered?

\_\_\_\_\_

17. At what point did you make your decision to accept a living donor kidney?

Did you know right away you wanted to accept and did not  
need to think it over ☐

After talking to the donor ☐

After talking to medical staff ☐

Only after talking to medical staff and completion of tests ☐

18. At the time you made the decision to accept a living donor kidney were you aware  
of any potential risks to your health?

No ☐ Yes ☐ If Yes, what risks were you aware of ?

\_\_\_\_\_  
\_\_\_\_\_

19. At the time you made the decision to accept a kidney from a living donor were you  
aware of any potential risks to the health of the donor?

No ☐ Yes ☐ If Yes, please explain

\_\_\_\_\_  
\_\_\_\_\_

20. At what point did medical staff formally ask you to make a decision, if at all?

\_\_\_\_\_  
\_\_\_\_\_

21. Did you at any point reconsider your original decision to accept a kidney from a  
living donor?

No ☐ Yes ☐ If Yes, why?

\_\_\_\_\_  
\_\_\_\_\_



22. Were you offered the chance to simply change your mind without your family knowing the real reason (ie: would the hospital give you a medical reason?)

Yes ☐ No ☐

23. Was there more than one person offering to give you a kidney?

Yes ☐ No ☐ If Yes, who were the other potential donors?

24. How did you and the medical staff decide which donor to accept a kidney from?

Medical reasons ☐

Other reasons ☐ please specify \_\_\_\_\_

25. Did you feel pressurised by anyone to accept a kidney from a living donor?

No ☐ Yes ☐ If yes, who?

Donor ☐ Member(s) of your family ☐

Medical staff ☐ Member(s) of donor's family ☐

Other ☐ who? \_\_\_\_\_

26. Did you experience pressure NOT to accept a kidney from a living donor?

No ☐ Yes ☐ If Yes, by whom?

Donor ☐ Member(s) of your family ☐

Medical staff ☐ Member(s) of donor's family ☐

Other ☐ who? \_\_\_\_\_

27. Did accepting a kidney from a living donor ever cause any family conflict?

No ☐ Yes ☐ If Yes, could you explain

28. On a scale of 1 to 5 how difficult would you say your decision to accept your kidney was?

1---Extremely difficult ☐

2---Very difficult ☐

3---Quite difficult ☐

4---Not very difficult ☐

5---Easy ☐



29. What were your main worries about accepting your kidney?

Were you worried about;

- Your own health/medical complications☐
- Health/medical complications of the donor☐
- Financial implications to the donor of donating a kidney☐
- The effect on your family of accepting the kidney☐
- Whether the transplanted kidney would work☐

Did you have any other worries?

Impact of Donation

30. Who discussed with you the possible positive and negative consequences of having a kidney transplant?

- Nephrologist (kidney specialist)☐ Surgeon☐
- Transplant coordinator☐ Other☐

If Other who?

31. Were any positive or negative consequences of having a kidney from a living donor discussed with you? What risks/benefits were you told about?

- Better match☐
- Pre-planned operation☐
- Earlier transplant☐
- Effect on donor's health☐

Any other comments?

32. Did you feel that the medical staff tried to persuade you in one direction or another? No ☐ Yes ☐ If Yes, could you elaborate

33. Did you seek information from any other sources? No ☐ Yes ☐ If Yes, where from?

34. At the time of the transplant what was your overall impression of the risks to your health?

- 1---No risk whatsoever☐
- 2---Little or no risk☐
- 3---A very small risk☐
- 4---Quite a risk☐
- 5---A big risk☐



35. At the time of the transplant what was your overall impression of the risks to the donor's health?

- 1---No risk whatsoever ☐
- 2---Little or no risk ☐
- 3---A very small risk ☐
- 4---Quite a risk ☐
- 5---A big risk ☐

36. How long were you in hospital for? \_\_\_\_\_ days

37. How long was the donor in hospital for? \_\_\_\_\_ days

38. How was your relationship with the donor before the operation?

- 1---Extremely close ☐
- 2---Very close ☐
- 3---Fairly close ☐
- 4---Not very close ☐
- 5---Not close at all ☐

39. Did this relationship change after the operation?

- 1---Greatly improved ☐
- 2---Improved ☐
- 3---Didn't change ☐
- 4---Got slightly worse ☐
- 5---Got much worse ☐

40. Do you think the donor thinks more highly of themselves as a result of giving you a kidney?

- 1---Very much higher ☐
- 2---A little higher ☐
- 3---No different ☐
- 4---A little lower ☐
- 5---Very much lower ☐

41. How has your health changed as a result of having a kidney given to you?

- 1---Greatly improved ☐
- 2---Improved slightly ☐
- 3---No change ☐
- 4---Worsened slightly ☐
- 5---A great deal worse ☐

42. Do you feel indebted to the donor in anyway?

No ☐ Yes ☐

If Yes, is this a burden to you?

No ☐ Yes ☐



Employment

43. Were you employed (outside the home) at the time of your decision to accept a kidney from A living donor?

No ☐ Were you;

Unemployed ☐ Retired ☐

Looking after family ☐ Full-time student ☐

Other ☐

please specify\_\_\_\_\_

Are you employed now?

No ☐ Yes ☐

If Yes, what is your job?\_\_\_\_\_

Yes ☐ 44. What was your job? was it physically demanding?

\_\_\_\_\_

45. What is your job now? is it physically demanding?

\_\_\_\_\_

\_\_\_\_\_

46. Do you feel that having a kidney transplant has affected your performance at work? No ☐ Yes ☐

If Yes, has it: Improved ☐ or Worsened ☐

47. Has this affected your income? No ☐ Yes ☐ If Yes, how?

\_\_\_\_\_

48. Has having a transplant affected promotion at work?

No ☐ Yes ☐ If Yes how?

\_\_\_\_\_

49. How long was it before you returned to work/returned to normal everyday activities after the transplant?\_\_\_\_\_

50. Did donating a kidney affect the donor financially?

1---A great deal ☐

2---A little ☐

3---Not at all ☐

What losses/expenses did they incur?

\_\_\_\_\_

\_\_\_\_\_

51. Did the donor receive compensation for losses in connection with the donation?

No ☐ Yes ☐ If yes, where/who from?

\_\_\_\_\_

\_\_\_\_\_



52. Taking into account your experiences of having a kidney transplant from a living donor would you go through the whole process again?

Yes ☐ No ☐

If No, would you prefer a transplant from a dead donor?

Yes ☐ No ☐

53. How satisfied were you with the level of support from your family?

1 Extremely satisfied ☐

2 Very satisfied ☐

3 Moderately satisfied ☐

4 Not very satisfied ☐

5 Extremely dissatisfied ☐

If scoring 3, 4 or 5 In what ways could the level of support have been improved?

---



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54. How satisfied were you with the level of support from the hospital?

1 Extremely satisfied ☐

2. Very satisfied ☐

3. Moderately satisfied ☐

4 Not very satisfied ☐

5 Extremely dissatisfied ☐

If scoring 3, 4 or 5 In what ways could the level of support, have been improved?

---

55. What are your views on the use of;

(a) closely related donors ie: parents, brothers, sisters

In favour ☐ Not in favour ☐ Not sure ☐

(b) Distantly related donors ie cousins

In favour ☐ Not in favour ☐ Not sure ☐

(c) Husband/wife donation

In favour ☐ Not in favour ☐ Not sure ☐

(d) Friends (non related)

In favour ☐ Not in favour ☐ Not sure ☐

(e) Strangers?

In favour ☐ Not in favour ☐ Not sure ☐

56. What is your view of buying and selling organs?

In favour ☐ Not in favour ☐ Not sure ☐

57. Would you have considered buying an organ?

No ☐ Yes ☐



58. Should any payment be permitted, for example to compensate for losses incurred by the donor?

No ☐ Yes ☐

59. Are there any other matters that you would like to mention?

60. Have you any questions?

61. Is the transplanted kidney from the living donor still functioning?

Yes ☐ No ☐

THANK YOU VERY MUCH FOR COMPLETING THIS QUESTIONNAIRE

QUESTIONNAIRE: ORGAN DONOR

Personal Details

use only

for office

Name \_\_\_\_\_ Male ☐ Female ☐

Address \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Date of Birth (DD/MM/YY) \_\_\_\_\_ Religion \_\_\_\_\_

Date of Donation (DD/MM/YY) \_\_\_\_\_ Age at donation \_\_\_\_\_

1. What is your relationship with the recipient?

Father ☐ Mother ☐  
Brother ☐ Sister ☐  
Other ☐ Please specify \_\_\_\_\_

2. Do other family members have kidney problems?

No ☐ Yes ☐ If Yes, please give details \_\_\_\_\_  
\_\_\_\_\_

3. Were you living with the recipient at the time of the donation?

Yes ☐ No ☐ If Yes, who else was living at home? \_\_\_\_\_

\_\_\_\_\_

If No, where was the recipient living? \_\_\_\_\_

\_\_\_\_\_



4. What was your marital status at the time of the donation?

Married ☐ Single ☐  
 Cohabiting ☐ Separated ☐  
 Widowed ☐ Divorced ☐  
 Has this changed since the donation Yes ☐ No ☐

If Yes, how? \_\_\_\_\_

### The Decision to Donate

5. How did you first become aware that the recipient needed a transplant?

Recipient told you ☐  
 Medical staff told you ☐ who? \_\_\_\_\_  
 Other ☐ please specify \_\_\_\_\_

6. Did someone ask you to consider donating your kidney

Yes ☐ No ☐ If Yes who asked?

Recipient ☐

Other family member ☐ who? \_\_\_\_\_

Medical staff ☐ who? \_\_\_\_\_

Other ☐ who? \_\_\_\_\_

If No, did you offer without being asked?

Yes ☐ No ☐

7. Did you know right away that you wanted to donate and  
to think it over?

did not need

☐

OR Did you make your decision only after talking to medical staff?

☐

OR Only after talking to medical staff and completion of tests?

☐

8. At that time were you aware of any potential risks to your health?

No ☐ Yes ☐

If Yes, what risks were you aware of? \_\_\_\_\_

\_\_\_\_\_

9. At what point did medical staff formally ask you to make a decision?

\_\_\_\_\_

10. Did you at any point reconsider your original decision to donate?

No ☐ Yes ☐ If Yes, why? \_\_\_\_\_

\_\_\_\_\_

11. Were you offered the chance to change your mind without you family  
knowing the real reason?

Yes ☐ No ☐



12. Were you the only person considering offering a kidney  
No ☐ Yes ☐ If No, who were the other potential donors?

13. Why were you the one who finally donated the kidney?  
Medical reasons ☐ Other reasons ☐ please specify

14. Did you feel pressurised by anyone to donate?  
No ☐ Yes ☐ If Yes, by whom?

- Recipient ☐
- Members of your family ☐
- Medical staff ☐
- Other ☐ please specify

15. Did you experience pressure NOT to donate your kidney?  
No ☐ Yes ☐ If Yes by whom?

- Recipient ☐
- Members of your family ☐
- Medical staff ☐
- Other ☐ please specify

16. Did donating your kidney ever cause any family conflict?  
No ☐ Yes ☐ If Yes, in what way?

17. On a scale of 1-5 how difficult was your decision to donate your kidney ?

- 1-----Extremely difficult ☐
- 2-----Very difficult ☐
- 3-----Quite difficult ☐
- 4-----Not very difficult ☐
- 5-----Easy ☐



18. What were your main worries about donating your kidney?

Were you worried about;

Your own health/medical complications? ☐

Financial aspects of donating your kidney? ☐

The effect on your family of donating your kidney? ☐

Whether the transplanted kidney would work? ☐

Did you have any other worries?

**The Impact of Donation**

19. Who discussed with you the possible positive and negative consequences of donating your kidney?

Surgeon ☐

Nephrologist (kidney specialist) ☐

Transplant coordinator ☐

Other ☐ please specify \_\_\_\_\_

20. Did you feel that the medical staff tried to persuade you in any way?

No ☐ Yes ☐ If Yes, please explain/elaborate \_\_\_\_\_

21. What risks were you told about? \_\_\_\_\_

22. Did you seek information from any other sources?

No ☐ Yes ☐ If Yes, where from? \_\_\_\_\_

23. At the time what was your overall impression of the risks to your health?

1---No risk whatsoever ☐

2---Little or no risk ☐

3---A very small risk ☐

4---Quite a risk ☐

5---A big risk ☐

24. How long were you in hospital for? \_\_\_\_\_days

25. How was your relationship with the recipient before the operation?

1---Extremely close ☐

2---Very close ☐

3---Fairly close ☐

4---Not very close ☐

5---Not close at all ☐



26. Did this relationship change after the operation?

- 1---Greatly improved ☐
- 2---Improved ☐
- 3---Didn't change ☐
- 4---Got slightly worse ☐
- 5---Got much worse ☐

If your relationship has changed could you explain in what way?

27. Do you think more highly of yourself as a result of donating your kidney?

- 1---Very much higher ☐
- 2---A little higher ☐
- 3---No different ☐
- 4---A little lower ☐
- 5---Very much lower ☐

28. How has your health changed as a result of donating your kidney?

- 1---Greatly improved ☐
- 2---Improved slightly ☐
- 3---No change ☐
- 4---Worsened slightly ☐
- 5---A great deal worse ☐

Please give details of how your health has changed

Employment

29. Were you employed (outside the home) at the time of your donation?

No ☐ Were you;      Unemployed ☐      Retired ☐

Housewife ☐      Full-time student ☐

Other ☐ please specify \_\_\_\_\_

Are you employed now?

No ☐      Yes ☐

If Yes, what is your job \_\_\_\_\_

Yes ☐ What was your job? Was this a physically demanding job?

30. What is your job now? is this a physically demanding job?



31. Do you feel that donating a kidney has affected your performance at work?

No ☐ Yes ☐ If Yes, how? \_\_\_\_\_

32. Has this affected your income?

No ☐ Yes ☐ If Yes, how? \_\_\_\_\_

33. Has this affected promotion?

No ☐ Yes ☐ If Yes, how? \_\_\_\_\_

34. How long was it before you returned to to normal everyday activities/work?

\_\_\_\_\_

35. If working in paid employment did your employers give you time off work?

No ☐ Yes ☐ If Yes, did you receive full wages?

\_\_\_\_\_

If No, was your job kept open for?

\_\_\_\_\_

36. Were you able to claim state benefits?

No ☐ Yes ☐ If Yes, what benefits were you able to claim?

\_\_\_\_\_

37. How has donating your kidney affected you financially?

1---A great deal ☐

2---A little ☐

3---Not at all ☐

38. What losses/expenses if any have you incurred?

\_\_\_\_\_

39. Did you receive any compensation for expenses/losses?

No ☐ Yes ☐ If Yes where/who from?

\_\_\_\_\_

40. Have you applied for life insurance since donating your kidney?

No ☐ Yes ☐ If Yes, did you have any difficulty getting insurance?

\_\_\_\_\_

41. Taking into account your experiences of donating your kidney would you go through the whole process again?

Yes ☐ No ☐ If No, could you explain why?

\_\_\_\_\_

\_\_\_\_\_



42. How satisfied were you with the level of support from your family?

- 1 Extremely satisfied ☐
- 2 Very satisfied ☐
- 3 Moderately satisfied ☐
- 4 Not very satisfied ☐
- 5 Extremely dissatisfied ☐ If scoring 3,4 or 5 what could have been improved
- 
- 

43. How satisfied were you with the level of support from the hospital?

- 1 Extremely satisfied ☐
2. Very satisfied ☐
3. Moderately satisfied ☐
- 4 Not very satisfied ☐
- 5 Extremely dissatisfied ☐ If scoring 3, 4 or 5 in what ways could the standard of support, or care have been improved?
- 
- 

44. What are your views on the use of;

(a) closely related donors ie: parents, brothers, sisters

In favour ☐

Not in favour ☐

Not sure ☐

(b) Distantly related donors ie cousins

In favour ☐

Not in favour ☐

Not sure ☐

(c) Husband/wife donation

In favour ☐

Not in favour ☐

Not sure ☐

(d) Friends (non related)

In favour ☐

Not in favour ☐

Not sure ☐

(e) Strangers?

In favour ☐

Not in favour ☐

Not sure ☐

45. What is your view of buying and selling organs?

In favour ☐

Not in favour ☐

Not sure ☐

46. Should any payment be permitted, for example to compensate for losses incurred?

Yes ☐

No ☐

Not sure ☐

47. If it was possible to buy a kidney would you have bought one for your relative?

No ☐

Yes ☐

48. Is the transplanted kidney still functioning?

Yes ☐

No ☐ If No, do you know why?



---

49. Have you any questions? or other matters that you would like to mention?  
Please continue over the page



## 2B: The EUROTOLD Semi Structured Interviews

### 2B(i): Dublin.

The practice of LDT in Eire has virtually come to a standstill over the last few years. At the sole transplant unit in Eire (Beaumont Hospital, Dublin) we were informed by members of the transplant staff that the supply of cadaver organs is increasing such that the demand for organs as a whole, and thus also the waiting list, has greatly decreased. In these circumstances the staff without having a formal policy of not using LDT have barely used it in practice. These 5 interviews represent a small sample of about 100 living donor transplants that have taken place at the centre. Since most of the interviews significant changes have taken place in the set-up of the unit. In particular some people interviewed mention not having counselling available at the hospital around the time of the transplant when now a counsellor is available for donors, recipients and their families - as well as those still at dialysis stage. The hospital also has a dialysis and transplant information officer.

The counsellor at the Dublin centre takes a person - centred approach to her work based upon the philosophy of Carl Rogers (see Appendix 4 for details of this approach).

### Interview 1.

The donor, Jane, and recipient, Sean, are sister and brother respectively. The transplant took place in 1979.

#### *1) Quality of decision making.*

I ask the Jane how she came to donate. She replied that she was the closest match in the family, 6 people including the parents and three other siblings offered to donate. I continue, "how does it feel to have donated?" Jane replies, "it's just an operation, when you're young you don't think of it. I watched him ill for 3 years. I looked after him because I was the only member of the family in Dublin at the time." I asked, "did you have any fears about donating?" Jane replies, "no." I continued "did they talk much about risks and benefits and so on?" Sean (the recipient) responded, "I don't think there was much risk involved what can happen with one kidney can happen with two you know." Jane adds, "A car accident is the only thing where you might damage one. There's nothing else.. I was very healthy." I asked Jane if it was a quick decision. She replied, "yeh, but I had a 6 month old child - it was a hard decision." Sean continuing says, "it was sudden all went through in a matter of 3 years. I'd never been in a hospital before 1976 (i.e. not for anything other than the kidney problems).

I said to Jane, "I'm trying to understand how you made the decision... did the hospital ask you - I mean how did things get raised at the time? Jane responds, "I could have refused right up to the operation... could have changed my mind - the doctors made me aware of that. I didn't feel any pressure.

(Note: It was unclear from the interview exactly why they preferred LDT to cadaver. Possible reasons are firstly that Sean's deterioration was fairly fast, secondly that it took him 10 hours, including the travelling to and from Dublin, each time he wanted to dialyse. Thirdly in 1979 LDT was generally thought to have a much better success rate than cadaver donation on the whole.).

Jane felt the information was "good enough" though perhaps "not as much as today." Sean said they knew the rate of success was much higher for the family. Jane added that they were not a perfect match and the doctors "would have liked it closer."

#### *2) Feelings after the donation.*

Nothing to add.

#### *3) Quality of care.*

I asked, "what is your view of the medical care?" Sean replies, "I would say the nurses and that are very good. I'd say it's probably not as personal as it used to be.. you're more a number now." They both associate this partly with the change to the new and bigger hospital. Jane says the care was "fine" for her and mentions that although she has had only one check up since the operation she feels that she doesn't need more.

#### *4) Quality of donor-recipient relationship.*

When I asked if they had got closer through the operation Sean replied simply, "well we've always been close." They added that the donation had not led to any family conflict.



### 5) *Quality of Life.*

Sean says, "I have a family of my own. It's been fantastic - the whole thing has served some purpose - given me the quality of life." I asked if he had any side effects he responds, "drugs affect the skin you know, other than that... I mean you wouldn't be a 100% but you don't think about it.. you forget about it" (he takes small doses of imurin and prednisilone). After the operation he stayed in hospital for 3 months with a blood infection. Sean says the kidney is still "working well" he feels that long term the drugs are probably a greater health problem than the possibility of the kidney failing.

### 6) *Other Aspects.*

Unusually the recipient was only born with one kidney. Jane did not get any money for her taxis and fares to and from the hospital. Jane says that she has had no problem obtaining life insurance, Sean says that it has been expensive for him "75 a month with no savings policy."

## Interview 2.

The donor, Mark, and recipient, Helen, are brother and sister respectively.

### 1) *Quality of decision making.*

Helen says, "my brother was a 95% match and it's so far lasted 14 years." I asked, "how did you decide to do a living donor or did that..?" Helen says, "well the doctor approached the family." Mark continues, "we all did the blood test. I went for a week of tests. They interviewed me asked if I was under 21 and asked if there was any family pressure." I respond, "how old were you?" Mark says, "20. I was quite happy about it - it was very easy - clear cut." I continued, "did they tell you about the risks and benefits and things?" Mark replied, "well of course they explained that there can be problems and put it in percent."

[Note: Mark explained to me that there were 3 other brothers of Helen in all who went for testing - 1 had the wrong blood level, another had had 2 operations already and the third he (Mark) was more histocompatible than].

I asked, "how do you view the overall standard of information?" Helen replied, "there was no counselling. After the transplant I found it awfully hard. You're back into the big wide world and you're out into society, living. When I had freedom I didn't know what to do with it. I am sure I could have done with counselling, there's a counsellor - Marjorie - here now. There's an awful lot of investigation going on now into the needs of the family through the kidney association." I asked, "what about the counselling before and during the process?" Helen continues, "there wasn't any." Mark adds, "well there was from my point of view but that was only because I was 20."

On the choice of living donation in preference to cadaver Helen says, "when I had my transplant cadavers were only 50% successful whereas LDT was 80% (and with this particular donor it was 95%). Nowadays they're kind of neck and neck the treatment is so good."

### 2) *Feelings after the donation.*

I asked Mark if he was happy with his decision he replied, "oh yeh." He added that he felt no loss in giving the kidney. Helen says to receive she felt "great" and added that "it did feel slightly imbalanced." I asked, "did it feel slightly alien?" She replies, "initially it did but not now... it's like it never happened the way it is - which is the way it should be."

### 3) *Quality of care.*

Helen said her care was "super," she later added, "they are all vey nice, they know all the patients on a first name basis."

### 4) *Quality of donor - recipient relationship.*

I asked, "has it impacted upon your relationship at all. Have you come closer through it all?" Helen replies, "ah yes, well we live in the same house." I asked if the donation had led to any conflicts within the family, Helen replied, "none." Mark continued, "no there aren't any - the only problem we had was who was going to get there first!" (we laugh)

### 5) *Quality of life.*

Helen says, "my kidney function is fine, small problems like a low pottassium level and stomach problem... I have warts. I also had a rash on my face. I work out - I cycle, play badminton do various things to keep fit. I'm not on cyclosporine I'm on imurin and prednisilone." She later notes that because of the quality of the match she is on a minimum of treatment.



*6) Other aspects.*

Neither is in favour of commercialization of organs. Helen says, "it's a dodgy situation." Mark feels alright about the idea of distant related and unrelated donors but Helen has reservations she is concerned particularly about the dangers of disease such as AIDS being transmitted.

**Interview 3.**

Billy, the donor is the father of Seamus the recipient who was a minor when he received the kidney.

*1) Quality of decision making.*

I ask, "what do you think of the support and the information and counselling involved?" Billy replies, "I didn't get any counselling but I didn't seek any help. There were so many people you could talk to that you didn't actually need to go for counselling. It's a good thing if you need it but we didn't." Billy insisted that his son, not yet a teenager, was involved in all the meetings so that he'd know what was going on for himself, "he seemed to handle it well so there was no problem. He's never been a really scared child... I let him go to the hospital on his own and if they wanted to do something he didn't want he'd call me and I'd come to the hospital.. I felt that from really young he was able to think for himself."

*2) Feelings after the donation.*

Nothing to add.

*3) Quality of care.*

Billy, "their on the ward the nurses were taking him to town to the pictures.. When he first transplanted the atmosphere at the hospital was like a family - the patients were helping the nurses.. you come in here and most of the doctors and nurses they are so human. So that's great because I think if you're really friendly with someone you have more confidence in them."

*4) Quality of donor - recipient relationship.*

Nothing specific said, Billy has been the primary carer for his son since his wife died. Their relationship seems unstrained and one in which Seamus does not have his autonomy greatly fettered.

*5) Quality of life.*

The transplant from Billy to his son has failed and so has another one. Seamus in spite of all this seems to have a positive attitude toward transplantation and life generally.

*6) Other aspects.*

Nothing to add.

**Interview 4.**

John is the donor - brother of Mary the recipient.

*1) Quality of decision making.*

I asked, "how do you feel about all the care and information - how was that?" Mary replied, "that was great, the doctors were great, helping you know." John added, "it's great... it wasn't a long time in the operation and recovery room."

*2) Feelings after the donation.*

Nothing to add.

*3) Quality of care.*

Both John and Mary said they found the care "great".

*4) Quality of donor - recipient relationship.*

I asked if the donation made for any conflict within the family. Both John and Mary replied no.

*5) Quality of life.*

Mary says that she was on dialysis three times a week beforehand, "it took an awful lot out of me - no energy whatsoever." Now she describes her health as "fine."

*6) Other aspects.*



Neither John or Mary had a problem obtaining life insurance. They both disagree with the buying and selling of organs.

### Interview 5.

The donor and recipient are identical twin sisters. I shall give them their real names since it would be very hard to cover their identity. Siobhan was the recipient and Linda the donor. They were both 13 years of age (nearly 14) at the time of donation. Their story has appeared on national Irish television and also in the kidney support magazine published by the Irish Kidney association. Their case was taken through a hospital ethical committee before the transplant could go ahead. One transplant surgeon at the hospital commented that although they were quite young it would be significant that the success rate for transplants of these sorts is vastly superior (about quadruple) to the average.

#### *1) Quality of decision making.*

Siobhan mentions finding it difficult to remember about the transplant as it was such a long time ago. Linda says, "I knew I'd have the best match.. I couldn't really understand the comotion of it." I asked, "was it more of an intuitive decision?" Linda replied, "the doctors explained to me what it would all involve but when I heard.. it didn't matter what was involved. With what she was going through of course I was going to do this." I continued, "was it scary?" Linda replied, "only beforehand - the only thing I feared was if it failed and someone else in the family would then be doing it. If it happens when you are older you are more aware of the side effects and that."

I ask, "do you remeber much about the process of information - the information they gave you?" Linda responds, "it was very good." Siobhan agreeing adds, "there was a lot of information." Linda added that she felt she didn't really need information.

[Note: In their joint article in "Kidney Kids" (published by the Irish Kidney Association) Linda says that the doctors made it quite clear to her that she could change her mind at any time and that would be alright, "but that thought never occurred to me. Helping Siobhan was all that mattered." She adds at the end of the article, "Siobhan had a new kidney - and a new life. I still had my sister."].

#### *2) Feelings after the donation.*

Linda says, "I'm glad for the fact that I've done it."

#### *3) Quality of care.*

They both feel that the quality of care was "great."

#### *4) Quality of donor - recipient relationship.*

The relationship between the two of them has always been close though it has changed. I felt that they had a very strong telepathic link. For instance as they recounted when one of them had a back injury the other, though in a different country at the time, felt back pains without having any back problems.

#### *5) Quality of life.*

Siobhan does not take any drugs now she says her health is "great." Linda says there have been no problems for her except that she was a little sore afterwards.

#### *6) Other aspects.*

Neither liked the idea of buying and selling of organs but both felt that the use of distant related and unrelated donors was fine.

### 2B(ii): Norway.

The interviews were conducted over a period of 7 days at Rikshospitalet in Oslo, Norway during the summer of 1993. I participated with a donor- recipient pair in all interviews. In all but the last interview a nurse was present to act as translator (Norwegian to English and English to Norwegian). A total of 26 people came for interview (13 donor recipient pairs). The interviews were all tape recorded and subsequently transcribed -in some cases in full and in others an edited version. The interviewees were chosen by one of the nephrologists at the hospital not as a random sample but with a limited amount of representativeness in terms of attempting to reflect several different outcomes (including cases involving rejection and one case involving rejection and loss) and donor-recipient relationships. Donor-recipient relationships included the more unconventional, such as brother's in law and spouses.

#### Interview 1 (through translation)



*a) The decision making process.*

The recipient, Andrew, states that his Kidney problem was familial and that consequently he did not want any of his family to be donors. He and his wife had heard about the possibilities for spousal donation so they discussed it. Both he and the donor, Jessica, had discussed the option of cadaver but felt that "it was so long a waiting list."

Jessica agrees with Andrew that she was scared but she also says she felt safe, "and hoped to help my husband Andrew .. I had seen so much.. after I had seen his illness I wanted to do something." She went to talk with a nephrologist and was in hospital taking all the tests, "I felt secure and wanted to give him that (the kidney) so it would not be so long a time for him to wait."

Andrew the recipient adds that he, "trusted the professionals" and, "felt secure." He later describes how he felt he could, "talk out and get answers.. it's easier here than in other hospitals."

Later Jessica adds that the quality of the information she was given was, "very good... I went into the nephrologists office, I felt peaceful. I could ask questions and I got all the information I wanted... it was very good overall." She also says, "I did not feel any pressure to be a donor, completely voluntary.. no threat or pressure from the hospital, my own decision."

Andrew, the recipient, felt he could have been given more information about the sex life afterwards.

*b) Feelings about the donation afterwards.*

Andrew had a rejection losing the kidney after six months and has been back on dialysis waiting for a cadaver kidney. I asked Jessica if the rejection was difficult for her, she replies, "I felt that I had given away something that was not good ..bitter.. down and I took it personally.. then gradually I went over the feelings and it was better with my husband." It was like a rejection of what she had given, "I was really disappointed and had expected it to go better .. and I knew that I could not get my kidney back! I had got information about that! So that was o.k.!" (we all laugh) But still I do not regret anything.. but of course it would be much better if he could have kept it."

[Note: this aspect of the interview shows clearly that although she didn't like the way things went she still didn't regret her decision. Some people consider that family donors, particularly or at least where spouses only give out of the interest of having the "family unit" work better again. Here I think Jessica had this motivation exposed by the "failure" of the kidney to work with Andrew which maybe leads us to the source of her feeling down, taking it personally, bitter etc. However the rest of the extract particularly that she didn't regret her decision suggests that she was at least partly motivated by the sheer value of the act of giving in itself.

*c) Quality of care.*

Expressed feeling above such as trust and good information but few statements more exclusively about everyday care. Jessica describes the hospital as a second home and that "they feel free that anytime anything happens they can just call- it has been important to me to feel the support.. they ask how I've been .. I feel they understand."

*d) Quality of donor- recipient relationship.*

They express no negative points although they say it has been hard for them at times, they feel they have spiritual strength and are able enough to deal with the sexual problems.

*e) Quality of life (some other aspects).*

Jessica says that they live day by day. She feels that despite all that has happened she still has a positive feeling. She does not describe having had any health problems since.

*f) Some other aspects*

The social security did not cover all the donors expenses - she would want it different. The feelings she had around Andrews loss of his kidney were also interwoven with the feeling she had for the death of their grandson a month later.

Interview 2. (translated)

*a) Quality of decision making.*



Translated from what participants discussed: Robert, the recipient, was ill and everything went quickly..the whole family came to discuss transplantation and in the beginning it was said that Robert's father should give the kidney but after a while they found that Robert's mother, Jane, had the best kidney. She didn't feel any pressure because she felt well it's a matter of the children, for her it was not hard to give the kidney.. the only thing she was afraid of was narcosis. Jane felt that the information before the operation could have been better - she had more questions about whether she would be alright with one kidney.. and some other questions as well. She was scared about the operation but spoke with the anaesthetist beforehand which was good.

*b) Feelings about the donation afterwards.*

Jane thinks it was a normal thing for a parent to do. Robert says he doesn't agree but hasn't made it into a big thing. When I ask Jane if she feels more love for herself for doing this she says yes. Not much here that indicates her motivation for donation.

*c) Quality of care.*

Translated as: they are really satisfied with their stay at the hospital.... They think that maybe the sick note from the doctors for just six months was not enough.

*d) Quality of donor recipient relationship.*

Not verbally expressed.

*e) Quality of life.*

Not anything extra expressed.

*f) Some other aspects.*

In contrast to the first interview this interview yielded little. This was partly attributable to the other participants speaking for long periods in Norwegian which were only translated as summaries.

Interview 3 (mostly spoken in English, little translation needed).

*a) Quality of decision making.*

The donor, Rowan is married to the recipient, Jenny. Jenny's long standing illness suddenly got worse after 20 years. She was asked by the doctor most involved if she had anyone in the family who would give her a kidney. She had two sisters but they refused, "which I was very disappointed about... and then he (the doctor) asked 'do you think your husband can help you?' and I asked him (the husband) and he said yes."

I asked Rowan about his feelings when he was asked he replied, "before it was a fact.. my feelings - for sure it's no problem if I can help her ... it was decided in one or two seconds, it was no problem." He says he felt no fear.

He said he was met by a doctor at the hospital who was explaining the risks and benefits to him but he says he thinks he interrupted her after not longer than 4 or 5 minutes saying, "oh no problem." He puts it that, "I really didn't hear.. I didn't want to speak about it because it was decided." (i.e. he'd already made up his mind.). Jenny felt there was not enough information about the rejection of the kidney but Rowan is not sure.

*b) Feelings about the donation afterwards.*

A guess at some of Rowan's motivation can be taken from the fact that he knew when he married. Jenny that she had kidney problems which would probably get worse.

He described his feeling after as one of having a good trip (with the drugs he'd been given), "like a wonderful movie." He described seeing Jenny for the first time after the operation, recovering as, "the best happening in my life.. I never had such an experience in my life." Later she had 2 strong rejections for him, "that was not a nice feeling" for 2 days he felt very down, "and if that had happened -to give a kidney and it should not succeed - I wouldn't like to think of that" He later adds that if that happened, "I think I could be depressed." Overall he seemed very positive about his donation, "I can recommend it," he said at a later point.

Jenny felt fantastic, very happy - to be able to have a transplant after her family had said no.

*c) Quality of care.*

Rowan says, "I came in and everybody was friendly- it seems that everyone appreciated - friends and other people in the hospital, the doctors and the sisters they cared very much about me.. very nice experience.. exciting also. Jenny says she felt safe at the hospital, "all the time" over the 20 years she had been there.



*d) Quality of donor-recipient relationship*  
Not expressed specifically.

*e) Quality of life (some other aspects).*  
Rowan had some health problems afterwards with a hospital virus, "that was the only thing."

*f) Some other aspects.*  
Little to add.

#### Interview 4 (translated).

*a) Quality of decision making.*

The donor Jim is the brother in law of the recipient John. John had had a long history of illness. His brother was going to give a kidney but John thought that because his brother was, "rather hysterical" he thought it, "would be too tough for him... Then his brother in law without any question was looking at his papers from the military and was saying by himself that 'we have the same blood group maybe you can have my kidney.'"

Jim came out alright on the tests and donated. I asked him if it was easy for him to make that decision he said, "it was no problem but I just had to lose 16 kilo's before they could put the knife in me!" (chuckling)

I asked him what he knew about the risks involved he replied, "I was in hospital for a week before the operation and I feel that I got all the information, that I didn't miss anything." Though he later adds that from his previous experiences he doesn't trust doctors. (John felt the opposite on this point).

*b) Feelings about the donation afterwards.*

I asked Jim if he was glad about everything he responded "he (John) got on his feet again (chuckles) that was the main thing. I haven't put much energy in thinking around the psychological things in transplation to me I just took the decision and that was it." John said it was special to him.. that otherwise maybe he would have had to wait a long time for a kidney because of his difficult blood group.

*c) Quality of care.*

Nothing expressed other than comments on information stated above and Kim's feeling that the hospital was disorganized over one aspect - they didn't find him a place to sleep after the operation other than in the corridor.

*d) Quality of donor-recipient relationship.*  
Nothing specific expressed.

*e) Quality of life (some other aspects).*  
Jim expressed no concerns about his health since.

*f) Some other aspects.*  
None to add.

#### Interview 5 (translated).

*a) Quality of decision making.*

Ruth has received a kidney from her mother Helen. I asked how the decision came about. Helen replied "it was a natural thing it came from ourselves.. we knew this was possible" Ruth (rough translation) said "I was so weak around the time of the transplant.. I felt I didn't have much strength to think about it. I knew there were better results but also in a way it was the doctor who took the decision because he realized there was a hurry to get a kidney. I think it was terrible for my mother to have to go through the operation as a healthy person... they didn't feel any pressure"

I then asked Helen what she knew about the risks she replies, "I felt that I knew everything" and specifically, "I knew I might have pain afterwards, that I might feel sick ... about the possibility of narcosis." Ruth felt "maybe I could have been informed more that I would need to take a lot of medicines.. and more about their side effects... and depression" though later she adds that, "I have a lot of confidence with the nurses and the doctors, they are small gods for me!"



[Note: That Ruth says that in one sense she feels it was the "doctors decision" based on the "hurry to get a kidney" - what did Ruth mean by this? It seems that she had almost handed over decision making to the doctor].

*b) Feelings about the donation afterwards*

I asked Helen if she sometimes felt empty without the kidney. She replied "no."

I asked her how she felt about what she had done, she said, "I feel that it's an important thing."

Ruth felt like she had been given "a second life" and added later "I'm more concerned about the small things in life.. I have longer time to see things.." "I'm nearer of the day today" (living more in the now). I said, "it sounds somehow more free- more spontaneity." Ruth replies

"uhum."

I asked Helen if things had changed for her she replied, "I'm just happy that it goes well with my daughter"

*c) Quality of care.*

Nothing expressed except for what Ruth mentions above about being generally confident with the doctors and nurses.

*d) Quality of donor-recipient relationship.*

Nothing specific expressed.

*e) Quality of life (some other aspects)*

Helen expressed no concerns about her health. Ruth (see b above) talks about having a second life.

*f) Some other aspects*

Ruth had little sight left which was connected with her diabetes - she didn't express any loss of sight being caused or connected with the transplantation itself - unlike the one person who was diabetic out of the Leicester group.

Interview 6 (not translated).

*a) Quality of decision making.*

Hilary the recipient describes how she spent much time sick and was on dialysis. I asked her "did you hope for a nekro kidney- a cadaver?" She replies "no my husband was ready when I needed it." I turn to her husband, Alex, the donor and ask "uhmm.. did that come from you then, the decision?" Alex replies, "yes it came from me. No err .. protests from anybody ... this was voluntary, no pressure from anybody. That's O.K., and the family afterwards they said that it was great that I did it." I later asked Alex if he had fear when he gave the kidney. He replied, "no, not much at all... beforehand we were shown a film about this thing ... but it didn't frighten. And before the operation I was quite calm. You see the doctor talked about it... quite simple.. it was very good- the doctors to talk about it beforehand, here in the hospital." "a good communication?" I enquire. "Yes" replies Alex. Alex continues "I feel very well that they took care about us."

Alex was "the only one" who came forward. Hilary explained that they had a son but that he was dying and couldn't give. "So I was the only one in the family and I was very glad," Alex said.

*b) Feelings about the donation afterwards.*

Alex said "its sweet" (to have done this). I asked Alex if he "felt slightly lower after the operation."

Here I was referring to a possible down/depressed sort of state but did not make that clear. Alex, I think took it that I was referring to a more permanent state of being, replying "I don't feel lower, I don't feel reduced in any way." This in itself I think is useful in perhaps suggesting that donating had no negative impact for him.

I inform Alex, "I'm trying to catch your feeling about giving the organ." He replies, "I feel nothing special I manage very good with the one I have so I don't think about it. If something should happen and I can damage the other one it will be dangerous.. but I'm so old the risk is small. I don't open parachutes or handgliding or anything like that! (we laugh)."

Hilary adds, "my doctor said he (Alex) is the right person to give - he will have back.. I was nothing and he will get back a wife"

Me: "also, to me, if it hadn't worked it would be a special thing - is this how you are feeling?" Alex: "Oh yes, we didn't know when we started that it will work, we didn't know when we started.. if it had



not worked well that was bad, but it was a try and I thought that was very important.. and maybe she could get a nekro, and I had done my best - nothing more to say about that."

Hilary mentions still having "hanging over her head" the knowing that her old kidneys will need to be taken out later on. She feels stronger and "very happy" with what has happened.

*c) Quality of care*

Alex says, "I feel very well that they took care of us"  
Other information expressed in part a)

*d) Quality of donor recipient relationship.*

They have been together for 50 years. I asked them if by being in this experience they had come closer. Alex replies, "ah yes, more - after this we having something together" Hilary said that, "one day we will be one... we must think that one day one of us will disappear." She later says, "we have really a good life together- and he is really quite special he is so kind and good to me. And I don't complain!" (she is crying - "tears of happiness" I say, yes she says).

*e) Quality of life (some other aspects).*

Hilary (as for most recipients) has a freer diet more free now than before. Before the operation, Alex said, she was just skin and bone. Hilary has difficulties such as with her bones (cortisone?) she expressed these in the context of talking about the side effects of the medicines but added that "some of the difficulties may be the age not the medicine."

*f) Some other aspects.*

Alex felt that all his expenses had been covered by the social. Alex, expressed that the cut that was made was "a little harm" but that was over in a fortnight and then he was o.k.

**Interview 7 (translated partly).**

*a) Quality of decision making (partly translation partly spoken directly in English).*

I said to Anna, the donor, "I wonder about the process of how you came to choose the kidney." Anna replies that "they (the doctors) wrote to the family - my mother and father and the other sister I think- and they checked our group and they found out I was the most like her so then they asked me."

Me: "uhum.. Did you discuss in the family if you prefer nekro (cadaver) or living?"

Anna: "No."

Me: "You just thought living was.."

Anna: "Yeh."

Me: "Better?"

Anna: "Yeh. They never asked me about nekro."

Alfhild who is translating elaborates, "They knew about it but it was never really talked about it."

*c) Quality of care*

Nothing to add

*d) Quality of donor recipient relationship*

Nothing to add

*e) Quality of Life*

Anna, couldn't walk for a time and felt exhausted. Now she describes her health as "great." Caroline got a reaction (rejection) afterwards - the response of Anna to that is detailed in a) above. Caroline says the kidney works "very well" now and finds it "incredible how healthy it's possible to be"- now she's "been healthy more than she has been sick."

*f) Some other aspects.*

Nothing to add.

**Interview 8 (generally translated).**

*a) Quality of decision making.*

Joanne, the recipient, and Tony the donor are married to each other.

Joanne through Alfhild: "I was very weak and just at the limit for starting dialysis and then the doctor asked him (Tony) if he wanted to give the kidney if the match was right and the first tests were fine and showed that



it was possible and then it just went on. I had second thoughts about it because I was scared what would happen to my husband during surgery..

Me: Did the doctor speak about the risks and ...(fading away).

Joanne and Tony through Alfild: "We think the information was very good and we got very much information and it went alright.

I ask Tony if they discussed any alternatives to him donating, Joanne replies, "I have a sister but she's not so healthy so it was not any alternative."

Me: "and the nekro (cadaver) kidney?"

Joanne: "In the beginning I thought that I had to wait for that, but there was a waiting list"

Me to Tony: "So you felt it would be better to give your kidney?" Tony nods in agreement.

Me: "Was it er.. I'm trying to understand how you made this decision - was it a quick decision or..?"

Tony: "No second thoughts, it was an easy clear decision." He says that he knew the operation was more serious for him (than her). He adds later that, "since the relationship has been so good it has been all so natural to do."

Joanne explains that they felt good that they could prepare, had more control over timing "and we heard that the risks of rejection of the kidney were less with a living donor than with a nekro." Joanne feels that it's good that husband-wife can be a living donor pair "because they have such a long waiting list."

*b) Feelings about the donation afterwards.*

Tony says it was a "very natural" thing for him to do. He says, "I'm very satisfied." Later he says, "I don't regret it - I never had any grief about the loss of the kidney. Joanne says now she doesn't think so much about it "since it has gone all so fine."

*c) Quality of care.*

Joanne finds it a special year for her even with the surgery "because I have met many nice people.. it has been a very good experience." She finds the staff very nice, the follow up good and that they get all the information they want.

*d) Quality of donor recipient relationship.*

Expressed above (part b) by Tony that relationship has been good.

I later asked if the relationship had come closer for them both with this experience. Tony replies that it was very close and maybe in some ways has now been closer.

*e) Quality of life (some other aspects).*

Tony was "out only for six weeks after" for which he got compensation from the social and his employer. He says his health is "fine." "No" complications. Joanne also says she feels "so fine" - though mentions being bigger in the face through cortisone and having less endurance "but I have to respect my age also"

Joanne expresses having a second life after the operation with more freedom.

*f) Some other aspects*

They suffered 'no financial hardship' as a result of compensation as mentioned in part e).

Interview 9 (rarely needed translation).

*a) Quality of decision making process.*

Caroline, the donor, has given to her sister, Mary. Mary describes how she has rheumatism and then connected with that she got a kidney disease 10 years before she was transplanted. When she was in hospital with the situation becoming more acute she describes how the doctor said "'you're going to need a kidney have you any other relatives?' and I said I have some sisters and he said best thing to ask them yourself whether they are prepared to give." She met two sisters and a brother - a sister and a brother offered to go for tests, the other sister wasn't suitable as she had a disease.

I asked, "did you discuss the possibility of a nekro kidney at all?"

Mary replied, "No, because the family was the first thing to try and if none of them was suitable.. then afterwards .. but the family is the first thing."

Me, "for you or..?"

Mary, "for everyone, because er it's the best results if you can have one with a good match."

(is she meaning a 100% match situation or does she view results of 50% matches as still better on average than cadaver - interesting whether many people know of the fine distinctions or not - since in this situation I think they are crucial in the comparing of success rates).



Caroline: "Our brother had a different kind of blood so he wasn't good - so it was only me left (she laughs). Well really I had no choice, yes I think so- I mean I'm healthy, I've been healthy all my life but it was a hard decision because I'm rather scared of hospitals... so it was rather hard- I have been healthy all my life and she hasn't." (these feelings of no choice and of her sister being less healthy could be interpreted as guilt being the motivation perhaps combined with a sense of duty. Being in the interview myself I did not get a sense that either of these feelings, or both combined formed a major part of her motivation).  
 Caroline: "Yes, yes and even if I said it was rather hard because of my situation inside me and my .. fear of hospitals.."

Later I said to Caroline: "I haven't yet got a picture of how the information was for you - the risks, the benefits and the psychological side too"

Caroline: "Well I came in here and I had a lot of tests.. they all proved I was quite sound (she smiles) and I was talking to some people sometimes and doctors and they said I didn't have to do this thing it was my own choice - I didn't have to, but I always thought what sort of a life should I have afterwards if I said "little sister I'm not going to help you, do whatever you will but me strong lady I'm going to live my own life. I couldn't live with that so I had no choice - not really."

Alfhild: "But did you get the information from the doctors?"

Caroline: "No, I didn't ask - I didn't want to know too much about hospital things, no."

Mary: "you dont like details."

Caroline: "No, no, no."

Me: "Did they (the doctors), come and ask to give you details or..?"

Caroline: "Ee, well you know the day before the operation they told me things but I don't know..er.. perhaps I could have asked more but I didn't like to know.. because that's my feeling inside- I don't like hospitals, I don't like to know I have blood running around my body- I don't like to feel that (she laughs)."

#### *b) Feelings about the donation afterwards.*

Mary says it was "a fantastic feeling when you are out of the operation." She feels that sometimes after the operation the doctors forgot they were dealing with people. Mary also feels that if she hadn't asked her sister would not have got any control.

#### *c) Quality of care.*

Mary expresses one or points of complaint about the human contact as above and says she feels that nobody paid much attention to her feelings after she had gone home shortly after the operation.

Caroline also had complaint but that was more in regard with how she had been treated at her local hospital.

#### *d) Quality of donor recipient relationship.*

Little expressed directly on this point - Mary was concerned much that Caroline, who had been her best help through the kidney problems, came to be directly bound up in the problem by being a donor. A person suggested to me something to the effect that where one family member has rheumatism she can become quite fixed in the "ill role" with other family members quite fixed in the "supporter role" and that this can become an unhelpful pattern if ingrained. I had very much wanted to hear equally or more of Caroline as the donor but the interview became very much more oriented around Mary - I wonder given this if Mary and Caroline feel to any extent that their relationship is ingrained in such a way or have a very different understanding of their relationship.

#### *e) Quality of life (some other aspects).*

Mary says she gets some side effects with the cortisone and other drugs. Caroline, when asked by Alfhild whether there had been any change in her life merely said, "oh I don't think so! (we laugh a little) when I sleep on this side I feel my wound.. but it doesn't hurt.. and now I must lay on the other side in bed." Caroline had a cold and stomach cramps for a time.

#### *f) some other aspects.*

Little to add.

### Interview 10 (translation generally not needed).

#### *a) Quality of decision making.*

David has given to his son, Simon. David explained that Simon knew he had had this disease for 8-10 years but that suddenly it became a real problem about a year ago and that his state was such that the doctors said he would have to have a transplantation in 1992 then he goes on to say "and concerning the - perhaps you have come here for to ask why - or how was your decision to donate .. and I think in any country if a father is asked it, you only could give - your not allowed to say no - naturally as you have brought up the child it's part of it.."



Me: "it's part of the process of caring..?"

David: "Yeh, I would say so .. when you are explained medically that you can make it just as good with one kidney it's no problem at all."

Me: "What was it like then.. explaining all the risks .. how was your information?"

David: "Well I think it was quite well explained to my understanding.. very well explained .. and also the rate of success for live donors was about 90-92% - they had very good statistics on that.. so er .. and for the donors situation."

Me: "Was the donors rate of success then something that influenced you to give rather than say have a nekro kidney?"

David: "Well er, we never reflected on that position at all because we certainly were told also that if we should take a nekro donor we should have to wait one year or more to do this .. and in the meantime he (Simon) would have to go through dialysis for this period and with that risk.. and also a quite lower rate of success if you have a nekro donor.. so the decision was quite clear." David says he felt no fear, felt relaxed and everything happened very quickly. Later I asked David if anyone else in the family had considered donating he replied, "Oh yes, the whole family except the youngest brother- he's too young- 15 at that time. Simon's sister, at that time 22, was tested as well as the mother." (and one of Simon's friends).

#### *b) Feelings about the donation afterwards.*

Me: "I wonder for afterwards.. how you felt about your decision and how you feel now... people say they have different feelings afterwards."

David: "I know, I heard about that... Nothing special.. but happy that this had been possible ... I would be very sad if I lost one of my kidneys but when it's been removed and it's been used for the benefit of a close relative then of course I'm happy for that.. so er, as a total for me it's been quite a natural process.. not too much thinking of it afterwards.. of course it has been a very exciting period when we have had these rejections.. I say we! (we all laugh) but er.. that is perhaps like it's so close that it's we, us, not me and him.. it's so joined.

Me: "It's something you've gone through close together. Did you have a period of feeling down afterwards. of feeling low?"

David: "No." later David says: "One thing that has come up is that Simon has not thanked me and I'm happy for that because it's so natural."

Me: "To me though it still feels quite a big thing and a special thing - is it not..?"

David: "I think many relatives and friends they felt it more that way than I did myself- I just did what I had to do- of course it's a big thing but I didn't feel it was that big.. no special feelings about it. Perhaps because I am a scientist myself and I look at it more from a scientific point of view than an emotional point of view."

Me to Simon: "I get the feeling that you have taken this experience and used it to grow."

Simon: "Yes, I would say so, I learn a lot about me and my friends.. and I look on life in another way.. when I got in the hospital I was very ill.. I was very bad.. very high protein in blood- 1600!"

#### *c) Quality of care.*

David: "When it happened I felt quite safe that we were in good hands" and later "the doctors they have done a marvellous job...The hospital took a really good action in this - I'm really impressed of their ability to do this quick and efficient.." (Simon gave an "umm" in agreement)

#### *d) Quality of donor recipient relationship.*

Me: "And I wonder for each of you how er.. you feel your relationship has been since.. do you feel it's grown stronger."

Simon: "Yeh stronger."

David: "Yeh, perhaps." (cautious about making definites here I think as opposed to throwing cold water on what Simon had said.)

#### *e) Quality of Life (some other aspects).*

Simon expresses having some problems with rejection afterwards, but over 2 or 3 months since the last one, "it's just fine - I would say the recovery has gone slow but fast enough for me." He later speaks of the side effects he has had such as problems with his bones from cortisone. Later he agrees with my expressed intuitive feeling that he "had taken this experience and used it to grow," he says he "looks on life in another way (now)."

David expresses how Simon's intestines encircled themselves and he consequently needed to be reoperated on later- "but that can happen to everybody I think in such a big operation, so it's no complaints to the hospital."

David himself took "some time to recover.. I had some pains for quite a long time.. due to one of the rib bones being removed."



*f) Some other aspects.*

David spoke about the political aspects of transplantation saying that dialysis costs the community "enormous amounts of money" and that some things could be better done to encourage transplantation such as with living donors to pay their travel tickets to and from the hospital and to ensure that full compensation is paid for loss of earnings.

Interview 11(translation generally not needed).

*a) Quality of decision making.*

Lynn is the donor and Philip the recipient. They are married to each other. Philip had a heart operation at which point problems with his kidneys were discovered and he went onto dialysis.

Me to Lynn: "How did it come to you I wonder - like the evolution from this point until you decide- umm I wonder how you came to decide to give?"

Lynn: "Umm, I knew of the two possibilities of course and we decided that we would see if I could do this one.. so umm I don't think we decided at that moment, we decided to see the results of the investigation and then take the decision."

Me: "Were there any other alternatives for living donors?"

Lynn: "We have 3 children but we didn't want to have them give their kidneys?"

Me: "Too young?"

Lynn: "Yes."

Philip: "...so we decided to have the complete testing to see how we corresponded with regard to tissue correspondance.. and we also decided if it were not good we would prefer another donor so we decided to wait until everything came out before we decided the kind of transplant to use.. but we also knew that there were a lot of people waiting for a kidney so umm.. that was another important (issue).. so if she could give a kidney somebody else could have a kidney too because there's a lack of kidneys - - (to Lynn) so you thought it would help the list for waiting?"

Lynn: "and I was thinking that it was not necessary for him to wait so long time to get a kidney."

Philip: "what Lynn was afraid of was that it would interfere with the emotional situation between us.. it has not been a problem I think."

Me: "Did you discuss this then with the doctors?"

Lynn: "Yes they informed me about the possibility of problems."

Me: "And the physical problems too?"

Lynn: "Yes."

Me: "How did you feel about the information and communication?"

Lynn: "Oh I think that was rather good, I think they spent time to explain and to.. but I was very scared of course.. I don't know if I -if it was possible to take all the information."

Me: "Yeh, umm, umm. So it was a hard time for you?"

Lynn: "it was not so hard really .. it was a chance.... we had a chance."

Philip says that Lynn's operation was harder in terms of recovery than he had expected and harder than the doctors had described but later added that the hardness of recovery could have had to do with her age, hard job and looking after an old mother living nearby. I asked Lynn if she felt she could have been better informed as regards the "hardness" of the operation. She replied, "yes - perhaps."

*b) Feelings about the donation afterwards.*

Me to Lynn: "How do you feel about your decision now?" Lynn: "Glad, of course. I think it was of value to me - I do something because this was the only thing I could do for him." Later she adds, "talking of the relationship between.. I have no feeling of loss.. not at all. I was a bit sorry because I was healthy and I had a strong body and I didn't like the idea of them cutting me with an operation.. that was a bit difficult but no other things."

*c) Quality of care.*

Philip said, "the staff at the hospital is very kind and friendly and warm people always feeling that they want to help us in every respect."

*d) Quality of donor- recipient relationship.*

Me: "So how would you say it's been in your relationship since.. through this experience.. would you say it's helped you to grow or..?"

Lynn: "Between us?" Me: "Yeh."

Lynn: (laughing) "It's still good, there's no difficulty- we can talk about it and laugh, make jokes."

Philip: "But we had a very good basis (beforehand) .. I was thinking how would it feel to have the part of another person within my body but because it's hers that's a good feeling."

Me (empathy not question) : "Doesn't feel too alien."



Philip: "No, (agreeing with my statement) I think it's quite a natural thing."

Me: "I wonder sometimes, and I wonder here if this has helped the kidney stay.. you know your feelings seem to be that it's not alien and it's not something too strange so I wonder if this helps it stay and not reject."

Philip: "Yes, I wonder too.. so I don't think anybody can answer it so far but of course it's a very complex biological situation so.. probably it helps."

*e) Quality of Life (some other aspects).*

Philip says of his side effects, "it's hard to know actually - but no significant at least." He was up and about the day after the operation but as described above Lynn took a lot longer - indeed she is not back working full time now (8 months after the operation) though this may as be partly or wholly connected with other aspects such as age etc.

*f) Some other aspects.*

Nothing to add.

Interview 12 (not translated).

*a) Quality of decision making*

Mark is the recipient and Janet is the donor. They are married to each other. Mark's difficulties with his kidneys were bound up with problems with his heart which he had several operations on. The problems with the kidneys got steadily worse over a period of years

Janet: "All the children - we have four children - we had all to find out who would be the best donor but we would not like to have the children because they have there own family and their own health to think about and so we were happy that we could make good use of mine."

Me: "You didn't want to create a risk for them?"

Both Mark and Janet replied yes then Mark added: "A couple of the children were willing to give a kidney but they were denied by her (Janet) and I more principally rejected it- so I had had a good life already."

Me: "So if the match was not good would you have chosen maybe a nekro - cadaver."

Mark: "Yes that would be a possibility, yes."

Janet: "Yes."

Mark: "But there are some advantages with a family kidney I understand, they can make a date for the operation- well it suited us rather well and she was willing to give it and I got the best of hers!" (we chuckle)

Janet: "You see the children would give there kidneys but err they had there own problems.. and because they could use my kidneys - I thought I had very good health.. and the chance with the family was, Dr... told us, much better than with the nekro.

Mark: "Yes we understand that statistically they were more successful."

Me: "How did the idea of giving feel to you?"

Janet: "Oh, I felt very good, yes, I wanted to help him, he had very little chance because both the kidneys and the heart- he had so much problem- he was not looking so good."

Later I asked: "I wonder how you found the information and the communication with the doctors here...particularly before the operation."

Mark: "Yes, err I think the information we got was satisfactory ...most of the time." He goes on to describe that the information was given over a long time - the problems being long standing ones. He also notes a "radical" improvement in the information and communication from 1989 onwards as distinct from when he was having heart problems in the 1984 period. "The teamwork which the doctors did on my case all through 1989 and the first half of 1990 - cross discipline- very nice work done to me."

Janet: "The same for me - I got the answers I wanted from Dr... and he asked me if I was afraid and such things."

Mark: "... It has been handled in a very fine manner.. the feeling of their willingness to listen to us and so on.. er I think that was very important help to us- gave us a kind of feeling of security and so on." he later adds that the doctors had wanted a sibling to donate rather than Janet but that they gave way on that point and came more into agreement when they saw that Janet was a very good match.

Later I asked Janet: "Were there some details then for you as a donor about any risks for you?"

Janet: "Dr .... told me that perhaps I could feel a little weak - he asked me to come to him if I felt weak afterwards... He told me about complications."

Later Mark says: The hospital informed that we would have the possibility of getting a nekro kidney- they wanted us to use a family kidney but just informed us that this is also a good alternative - described the advantages about the decision not to let the children donate he adds: "principally I made the distinction, which very many do, that the one who had lived a longer time should be able to take more risks than the one who had lived a shorter time- I think that's generally accepted.

Me: And also perhaps they have their own family units too.. their own families..



Mark: Yes both of them- of course they are having there responsibilities in another direction, of course that's right.

*b) Feelings about the donation afterwards.*

Me: How do you feel about your decision now?

Janet: I am the same.

Me: Is it positive?

Janet: Yes I could have done it once more if necessary! I found I had two good kidneys and I thought well I need only one so I can give one

*c) Quality of care.*

as above.

*d) Quality of donor recipient relationship*

Me: And for you both has it helped your relationship to grow through the experience?

Mark: Our relationship? Yeh I would say that in some respects it's better... there have been no tensions because of the kidney giving. Sometimes of course (he adds jestfully) I am afraid that she should want it back! (we all laugh).

Me: It seems a very positive thing.

Janet: Yes very positive - I would recommend it! The spouse instead of the children if it's possible.

*e) Quality of life (some other aspects)*

Nothing further.

*f) Some other aspects.*

Nothing further.

Interview 13 (without translation and without translator being present).

*a) Quality of decision making.*

Margaret had kidney problems for around four years before transplant and seemed to have some preparation through this: "... in 89 my kidney function was very bad practically no function left at all and it was decided to do the transplantation but I had been introduced to the idea of transplantation several years earlier and the first time at Rikshospital - and I remember this clearly because I talked with Dr ... and so on and he said very lightly 'well don't worry because when your kidney's give out we just give you a new one. (we laugh) So that was kind of reassuring.. it happened over a long period of time.. there was nothing really acute about it so I was asked if, very carefully if there might be anyone in my family who would be possibly considering.. and so on and so forth and I said that I thought maybe and so on and so forth. So I put the question to my parents. (turning to speak with her father who was the donor) Remember we were at the summer house? And I sort of asked and that was a very good experience because both parents jumped up and volunteered! (we laugh) And I remember you saying very clearly sort of putting my mother down "no it's best that I do this because you know we need to be taken care of afterwards and you're better at that." So this was the medical decision.... I had no brothers and sisters so they were the only possible choices.

Me: Did you discuss the possibility of having a cadaver, nekro, kidney?

Margaret: No. Not really because they wanted to check out if either of my parents would be compatible.. that was the first step.

Me: Did you consider then the cadaver option?

Margaret: No it never came up because as it happens both my parents were suitable so the question was never really- I didn't have to consider. Of course now- if I lose a kidney now I would have to reconsider in that way but er- that's a whole 'nother story.

[She and her father, John, go on to add that it was a good match and that the doctor preferred his kidney and general health to Margaret's mother's].

John says that for him to donate was "very easy.. it was no problem whatsoever"

Me: How did you feel about er.. I guess there was communication and information at this stage?

John: Well we got a very thorough information at this stage - we got how they were going to operate also the risks involved - gave me some statistics.. er .. also gave me some possibilities.

Margaret had to come happily through the transplantation so this was very open er- I should say discussions.. good organization.. it was a very good atmosphere.. of course that depends very much on the doctor himself I mean the way he can generate confidence of course- that's a psychological aspect (of the



process). We were all very optimistic that this would go very well. I would say that I experienced no personal problems with that, I was not afraid- not at all, it was just a matter of course. That's how it is.

Me: Somehow then er just sort of.. the right thing to do.

John: Oh yes.. there's a problem that you have no other choice but er.. you were very glad also that you were accepted as a donor (laughing).

Me to Margaret: Did you find it also an open communication?

Margaret: Yes, but I do think that I may have shut out some of the information that I didn't want to know about. You know it was umm.. well basically I was very ill.. so I was not- I was restricting what I wanted to use my brains to cope with and somehow I did not er.. I mean I had free access to all kinds of information and all kinds of literature but I deliberately did not want to study the risks or anything or ask any questions about that because I just didn't want to know.. This seemed to be the solution. But I've been thinking about this later on - the information and of course all the information that had to do with the surgery itself would be with the actual operation and where it had to be faulty - was to what might happen or could happen or would happen afterwards because that is of course very difficult to give full information about because it's so individual. Some people experience great problems and some people have no problems or very few problems and in a way I'm quite grateful that they didn't point out all the various things that would happen to me because then I think I would have been less enthusiastic about the whole procedure but as these things happened afterwards now I'm here and now I can cope with them as they arrive- so I was perfectly satisfied with the information but then again I know that we might not be quite the average case because first of all we had very good access to the doctor - but maybe everybody has that - I don't know, but then we had access to other doctors as well because I live with a doctor and we have friends who are doctors and so on and so forth - so there was an infinite source of information all over the place and we're also used to processing information because of our work we process enormous amounts of information all the time so that may have put us in a kind of advantageous position. But generally I felt very safe and very comfortable... I think these are competent people who know what they are doing later.. "I think these are competent people who know what they are doing.

John: Yes, both before and during and after the operation you felt safe.

Margaret to me: But may I ask a question? Although you are doing the questioning! (we laugh). Then to John she says: You say that you had no choice and I think that I understand what you mean but isn't that sort of contrary to what the situation should be. I mean when.. isn't it supposed to be that before people become living donors.. shouldn't he have a choice.. I mean you felt compelled to do this.. or what do you mean by 'had no choice'?

John: I think first of all of course you have a responsibility as a father, you have to live up to that and you have to do the best for your own child.. that's one thing and er.. if I had been asked and given the possibility to say yes or no I would feel there's no question of yes or no in a situation like ours. This was, as I tried to put it, as a matter of course and on that point there was no question of a choice. We never had thought of doing anything.. I was I would say very blessed that I was able to do this sort of thing. It generated great happiness. One could say beforehand we should do it together, we should fix it, and then the question was clear, there were no obstacles it was go ahead. It was a very great day

Later coming back to the issue of choice I say: What I get a picture from, from earlier what you said and thinking from before also, is that.. umm.. when you say you have no choice that can be taken in two ways and I take it one way (here) .. because some people would say they have no choice and this mean't that they were like forced or pressured...

John (listening): yes but I didn't mean it that way.

Me continuing: yes. like this is a different kind of feeling of no choice.. you know that it was just the right thing.

John: Yes at that stage it (the choice) didn't exist and that way I was not given the choice in a positive way.

Me: Umm, umm.

Margaret: I have been thinking a bit about that - both my parents have a terrible sense of duty- you know a sense of duty to life in general.. and er er.. I saw that particularly right before we had the surgery.. and you know I knew that things could go wrong and I thought that that would be absolutely awful - I couldn't live with that but then I sort of remembered the situation at the summerhouse. I was sitting on the terrace over breakfast and I sort of put this question sort of timidly and I just remembered they both jumped in their chairs and said 'please I want to do this.' This spontaneous reaction was my proof that this was really something they wanted to do and not something they felt they should do from any kind of negative duty.. so I sort of cling to that (laughing) that was very important to me.

John adds that they (he and Margaret's mum) had known the question would arise for a very long time (i.e. sort of chance to prepare for being asked)



*b) Feelings about the donation afterwards.*

John: of course this is a wonderful experience it's not that so you want to to come into a situation where you have that sort of experience but you are in the situation and of course then it's enormously positive.

*c) Quality of care.*

Nothing to add.

*d) Quality of donor recipient relationship.*

Me: I wonder how you've both taken this in your relationship, how has it been for your relationship?

John: Oh we have always been very close.. I feel we are closer than before.

Margaret: Well I feel the same way we've always been close but we are closer than before and I think also that these past few years we've been talking about different things than we've been able to talk about before. To some extent we've always been talking freely about most things but you know it's even easier to talk about more fundamental personal things - feelings. Yes it's a feeling that we have done something together not many other people have and it worked out and here we are. But I can very easily see that if you don't have a very good relationship with a parent.. and the parent is doing this for you and there has been a very conflicting relationship.

John: Yes er.. if you do that from a feeling of duty then it must be a horrible thing to do for both the parent- the donor- and also the recipient.

Margaret: Yes because it's such an intimate thing to do also, if your relationship is not patterned (stable?) it could create animosity.

*e) Quality of life (other aspects).*

John: oh the pain was very small and I was very happy. 6 days after the operation and I was out of the hospital... no complications whatsoever.. I wish every other donor would come through as easily.

Margaret says she had some problems - an infection and rejection.. sick for many weeks.. but in a "matter of 5 or 6 months" she was back to work.

Me: Did you have any side effects at all?

Margaret: Ah tremendous - many, many side effects - all kinds of things..... I have chronic eye infections, I have skin infections,.... shakings..... quite tiring but on the other hand. I was more dead than alive before so much better and I felt.. the most important thing in what you've given me is that my brain functions again.. you know I feel I can think, I feel I'm creative and so on... before the surgery... I couldn't remember things which is terrible in academia you know! (we both laugh) .. stuck on a lower level of functioning.

*f) Other aspects.*

Margaret: I felt this was truly a gift of love because you also when you receive a gift like that there's no way you can ever escape the question how can I ever repay this? You know there's no way of repaying such a gift..... But then I felt so sure I mean when it's a gift of pure love there's no need to repay it because there's no measurement of these things.. They are beyond measurement and that also has made it easier for me to say thankyou and accept this because er.. there's just no way I can repay anyway so I don't have to bother about that - I just have to go on living and the best.. I felt that the best way I could repay this.. this wonderful gift really was to get well.. as well as I could as quickly as I could. So it was a tremendous incentive to.. to sort of recover.

## 2B(iii): Leicester.

The Leicester interviews were conducted over a period of one and a half years beginning in the summer of 1992. The 22 interview participants were those available during this period from a sample of Leicester General Hospital's donors and recipients. The Leicester centre has had a fairly active living donor transplantation programme, particularly in recent years. The interviews were tape recorded and were conducted in some instances at the homes of the participants and in some cases in a private room at the Leicester General Hospital.

### Interview 1 and 2.

John is the recipient and Helen, his sister, is the donor

*1) Quality of decision making.*

John says, "I was told I was a good match with my sister... next best to a twin. I just knew I'd be alright. I was excited about it. My sister was more than willing to give it to me." I ask, "was she scared at the



time?" John replies, "yeh, I think she was, she was on the other end of the scale where it was a bigger operation."

I ask, "how did it all come about because presumably there must have been a possibility for cadaver?" John, "well I s'pose there would...well obviously I wasn't very well. My sister didn't like seeing me poorly. She says 'well can't we do anything?' and the doctor says 'well there is a possibility that you can donate kidneys' and me sister says 'well can we have some tests.' My mum and sister had blood tests, my sister was better. My sister never once changed her mind.. the tests kept going and the results getting better and better."

I ask, "do you think she felt pressured at all to donate?" John replies, "I don't know.. she never told me she felt pressure. She never hinted to me that it was the right thing to do because it's your brother. Do you understand what I'm saying?" I reply, "not just because it's family." John affirming says, "yeh, that's right.. she never said she had to do it." I ask, "I'm wondering about what you were told about the risks and benefits..." John replies, "well you get to know about the drugs and things and that the transplants are not all successful.. they come and tell you obviously that it could fail - you tend to know because you've been living it - ooh years."

Helen, the donor said her decision was really "just a quick thing." I asked her how she came to donate and she responded "well I don't really know." Her motivation was not that clear during the interview but there did not appear to be any pressure and she did not regret her decision.

## 2) *Feelings after the donation.*

John says that after the transplantation, "you sort of go yeh! - it's great it's like I could run a mile.... could get tucked into them foods ... chocolate and sweets (we laugh)."

## 3) *Quality of care.*

I ask, "how did you find the people working on the ward?" John says, "well with the people working on the ward they are like a family - you know and they're really great - even the mardy one!" (mardy is a dialect expression, for a moody, grumpy sort of person). I respond, "quite sort of personal?" John says, "it is yeh, I was thinking the other day if ever anyone was to ask what I missed about dialysis - and you don't miss much! (we laugh) it's the actual time with the staff. Bent over backwards to help you. Not an ounce of complaint anywhere... you have to take yer hat off to 'em ..."

## 4) *Quality of donor - recipient relationship.*

I asked John how he felt toward his sister for donating he replies, "very close really... it's hard to explain really. I mean it was really good of her to do it. It's not an everyday thing it's a big thing.. you know a living organ. We've always been close anyway - you know big sis big broth.. we've been a good pair together."

I later ask, "has the transplant affected your relationship with your sister?" John replies, "no I don't think it has.. I never felt as if I'd had to do something for her.. I never thought 'you gave me a kidney so I'm indebted to you.. does that sound bad?.. but it's in the right context... she doesn't expect me to be like that... she's my sister and we're close so I'd help her anyway but I'd help her because we are close not because she's given me a kidney." I respond, "so it's not like paying her back," John replies, "yeh that's right.. she's done a great thing for me and I know that, but that's it. It's forgot sort of thing - not forgot, you can't never forget it but it's not that we dwell on it.. never really felt I had to pay her back."

The donor generally said she felt positively about donation but she did have a problem with the scar which hadn't healed well. She felt somewhat embarrassed about sunbathing because of the scar.

## 5) *Quality of life.*

John mentions having extra hair growth from the drug regimen which he says can be difficult for women, he describes himself as in continued good health though notes that his white blood cell count has gone up. The donor was in good health apart from problems relating to the scar.

## 6) *Other Aspects.*

John said he had no cultural or religious difficulties with the idea of transplantation. John does not agree with the buying and selling of kidneys.

## Interview 3.

Alan's brother lives in a different country and was not accessible for interview.



### *1) Quality of decision making.*

Alan begins by saying he had had rows with his dietician and problems of feeling not supported. He was on dialysis for 8 - 10 weeks before transplant. He continues, "I had problems getting information from the hospital.. my G.P. didn't know a lot about it either.. and only found out from my wife that I was having a transplant. He continues by saying that on dialysis he, "felt left in the dark.... there was no real information." He also felt that he got no support from the kidney patients association before and during dialysis about which he was, "a bit pissed off...No support whatsoever.. I never saw anybody.. apart from the renal unit itself." He later says that he is "very angry and really disappointed" about the association.

He later says, "when I had my transplant they came in, my brother was tested and then er.. the day before the operation I was told what was going to happen. I would have thought it would happen a lot earlier.. to actually explain what was going to happen." I respond, "so you wanted to understand the process and how it works." Alan replies, "oh yes exactly - still have - see how it would affect my brother. It was just explained the day before the operation.. I would almost say there was a lack of communication there. You see patients when they get a kidney from a dead person it's all a rush but I think that it's been explained beforehand.. see I don't know I've never really spoken to them we've never had real contact.. we've been kept slightly separate. I think one of the things missing is communication... they really still haven't told me the implications for my brother. I thought that there was something missing beforehand. Not just sitting there and being told by the nurse - you know it would have been nice if there had been a doctor there."

He continues by speaking of the need for a certain sort of communication. I respond, "it's more than something mechanical it's something personal." Alan responds, "personal yes - mean it's umm, it's like when my renal function went down - I don't know if it's anything to do with it but my sex life went down for about 2 years but nobody actually told me (about the possibility of this happening, why it happened etc.)... I mean I was 34, 35 then. It was a shock to me .. they never really ask about things like that until you come out with it... and you get no proper information from the doctors either. Alan later says that although he felt the service was very good technically he feels that one doctor treated his brother like a "piece of meat."

The match, Alan explained, was so good ("almost like twins") that he doesn't need cyclosporine. I asked, "I'm wondering how the process came about to your brother donating." Alan replied that he had initially been asked by a doctor if he had a brother who might be willing to take a test and maybe give a kidney. He was too scared to ask his brother initially but then asked and his brother said yes.

### *2) Feelings after the donation.*

Alan says that neither he or his brother have regrets about the donation.

### *3) Quality of care.*

"Apart from that," Alan says referring to the information, "the service here from the doctors and nurses has been excellent and then he later says, "what the hospital have done for me is superb."

### *4) Quality of donor - recipient relationship.*

Alan feels closer with his brother since the transplant. Alan also speaks about his relationship with his wife. He says that she gave him, "a hell of a lot of support." They had some difficulties in their relationship through the strain of everything.

### *5) Quality of life.*

Alan is not on cyclosporine and takes a relatively low level of drugs. I asked Alan, "do you value life more now?" He replied, "yes and no, I value my life itself yes. On the other hand I occasionally think living in England is depressing.. I like my life. Life has a different meaning now... it means a lot more to me now. You see before everything was going down and you don't know it - you see it happens slowly.. it just goes down slowly."

### *6) Other aspects.*

Alan says, "I had to pay my brother's air fare and salary which was about 2000 - in that case I had no support whatsoever.. If (my wife) hadn't been there I don't know what I would have done... The factory was extremely good to me." He later adds that the money he forked out for his brother to come over to England to donate the kidney "really broke us" and he would have liked help from the hospital with this. Alan feels that LDT should be expanded - more publicized.

[Note: the money he gave to his brother only covered expenses and it is doubtful that it could have acted as any kind of inducement].



## Interview 4 and 5

The donor, Elizabeth, and the recipient, Marge, are sisters. They were interviewed at separate dates. Elizabeth came to the interview with her husband.

### *1) Quality of decision making.*

Marge says that Elizabeth was very keen to donate, "she kept on and on about it saying, 'I'm going to give you a kidney,' and I said, 'no you are not,' it all started before I knew anything about it... when my sister came up for tests she met a doctor in the passageway of the ward and he said, 'how are you?' and she said I'm fine but I'm just beginning to wonder why I opened my big mouth so wide' and he said 'now look if you have any second thoughts the whole thing is off. Now are you sure?' and she said, 'of course I am' but I thought it was wonderful that having come so far they were quite prepared to stop if she had second thoughts."

I asked Elizabeth, "did your sister think about receiving a kidney through the donor card system?" Elizabeth responds that Marge's name was on the list, "they phoned up and she couldn't go at that time because she'd got an infection - which was just as well wasn't it - because apparently it was a 100% match - mine was with hers."

Elizabeth said that after she had offered she had thought, "oh no I've opened my great big mouth again" but added that after she had thought about it she did not have any doubts. Elizabeth explains that their brother had said, 'you can have one of my kidneys:' "so I said, 'well look you can have one of mine,' because I didn't think he would go through with it anyway. Then it was sort of a matter of waiting and 6 months later I had tests and we fixed up a date... It was funny really I didn't think about it it was just sort of a natural thing to do. I had complete faith in everybody here." She continues, "I didn't think I might die, I mean people exist on one kidney. I expect it will be a bit uncomfortable afterwards but uhhh - she's always done a lot for me and it seemed to be a natural thing to do." I asked, "so what about the brother?" Elizabeth replied that, "oh well he's rather arrogant - he and his wife are hypochondriacs. They've always got something wrong with them and he says - well I don't really know I never really talked to him about it - but Marge said, 'oh it's something to do with insurance so I said, 'oh! get his priorities right (ironic laugh)'... He just came in for the first blood test that they did."

Elizabeth was not that concerned about risks - she said, "you know people make such a great fuss about it but really it's not such a great thing. People have operations all the time - in fact it's better really because you are fit when you go in. You get over it quicker."

I ask, "were the risks and benefits and things explained to you by the doctors?" Elizabeth responds, "well I don't remember anybody saying anything about risks um - no they just told me straightforward this is what will happen and if they thought there was any risk at all they wouldn't have done it ..."

[Note: I find this comment a little confusing. Does Elizabeth know there are risks? She seems to have known that every operation has a risk, does she also know there may be a small extra risk in just having one kidney?].

### *2) Feelings after the donation.*

Elizabeth said, "I never think it wasn't the right thing to do." I ask Elizabeth if it was quite rewarding to see the kidney working straightaway in her sister. She replied, "yes." She later says, "I can't say I would have done it for a complete stranger, in fact I'm sure I wouldn't."

### *3) Quality of care.*

Referring to the ward Marge says, "they were really wonderful every one of them, they were so supportive - it's like a family in there. I've never seen another ward quite like it." Marge feels that her sister was discharged too soon. Elizabeth says, "what struck me when I came in was the enthusiasm of everybody here - they were just marvellous." She later adds, "I always felt hospitals were so impersonal but this one couldn't have been better."

### *4) Quality of donor recipient - relationship.*

I asked Marge how the transplant affected her relationship with her sister she replied, "well it's a very big thing to do, I don't know if there are many people who would do that.. we have always got on well.. I think we are closer." Marge also describes the support of her husband as very important in enabling her to get through it.

I ask Elizabeth if the transplant has, "changed your relationship with your sister at all?" She responds, "no we've always been very close." I continue, "I wonder has it brought you closer at all?"



Elizabeth responds, "um, probably better understanding. We're not at all the same - we always have got on well together. She doesn't approve of a lot of the things I do but then her way of life wouldn't suit me."

#### *5) Quality of life.*

Elizabeth describes not being able to sleep after the operation, she was only in for a week but continued to have a dull ache in her back for about a month. She describes her health now as "fine" - she is now 68.

Marge said that she didn't realize until after the transplant what a low quality of life she had been having. She later says, "it was like being reborn, I never would have believed that even in the first few days I could... I mean one of the first sensations was of being warm - to be glowing whereas before I'd always been so cold." Marge is on aziathioprine, prednisilone, blood pressure tablets and tablets for calcium in the blood (overactive thyroid) "that's nothing compared to what I was on she says." Marge describes the transplant as tremendous.

#### *6) Other aspects.*

"Were there any financial difficulties?" I asked, Marge replies that her husband was initially turned down for attendance allowance but eventually got it. She adds that she is very positive about live donations as a whole.

Marge feels that commercialization has dangers and her husband suggests, "I think it would be better left well alone really." Elizabeth felt that it hadn't really affected her financially. She felt there was nothing wrong with a stranger donating or with commerce in donation - "somebody gets paid and saves someone else's life."

Elizabeth in common with two other people I have interviewed describes having hallucinogenic experiences. In her case she thought she was dead, "all these brightly coloured lights behind my eyes... I think it must have been the drugs.. ooh it was horrible. Just sort of coming and going and not being able to focus on anything. I thought God I'm dead! Trying to get back and then drifting off to sleep again. I really thought I was dead at one time because I couldn't get hold of anything. I was frightened I thought God this is horrible. Bright yellows, oranges and greens. But then I went to sleep again and of course by the time you wake up again you're back. Thank God!" I ask, "what were they doing just sort of flashing?" Elizabeth replies, "yes, in lines, greens and oranges and then people's voices and you'd be alright for a minute and everything would be sort of back then off you'd go again... I don't remember anything about Friday."

### Interview 6 and 7.

Reza, the donor, has given to his brother Hassan.

#### *1) Quality of decision making.*

I asked Reza if the medical staff had told him about the risks and benefits of the operation. He responded, "oh yeh they did, yeh they did say that. I had done some study on it before going to England and as far as I know you can have a quarter kidney and if it works alright you'll be fine, there won't be any problem...obviously you have to be careful what you drink - I have drunk whisky and still been fine but I think lager and soft drinks is the best - there's no problem I don't feel anything different."

I asked Hassan, "how did you feel about the idea of having a live donation?" He responded, "obviously I resisted it because when I went on a kidney machine in 1978 I didn't want to go ahead - if something goes wrong. But that (a living donation) was always on offer but I didn't accept it, then in 1980 I had a transplant that failed and the complications afterwards, but I still resisted it for another 4 years but you get to a point mentally that you can't go on with dialysis, you feel weak. So really I was ready by 1984 lets put it this way! I'd seen a lot of people who had done it - in Iran they only do relative transplants. It was almost a perfect match it was that close. It was a major decision but I've never seen a record of anyone dying from a live donation... So if you like this was a comforting thought and also you felt safe in their hands. My operation was very straightforward but his was massive. They had explained everything to him, he had made up his own mind." Hassan also later expressed concern about the possibility of getting A.I.D.S through having another cadaver donation and preferred LDT in that he wanted to have "as little as possible drug wise."

#### *2) Feelings after the donation.*

I asked Reza, "how do yo feel about what you have done?" He replied, "I'm quite happy if he's o.k. - that's my main point - not just me, my brother, my mother, my father (are important to me) ... the main point is that he be in good health he can do what he wants to do because he was on dialysis 3 or 4 days a



week and didn't have any sort of freedom - he had to dialyse one day and rest one day - now he's not doing that you know he's doing what he likes to do. Before he couldn't eat, he couldn't drink he couldn't do anything and now he does what he likes - that's my main point." I continued, "do you feel happy in what you have done, leaving your brother aside?" Reza exclaims, "oh yeh, of course, really happy, very happy - if I had one more extra I could give to somebody else."

### 3) *Quality of care.*

I asked Reza, "what was it like with the doctors and nurses?" He responded, "oh they were fantastic - they did look after us really good, take care of me and my brother. Always we did appreciate them, really good, no problem."

I asked Hassan what the care was like at the hospital he responded, "The care was good, when I was on a dialysis machine in 1978 it was very good - I don't know if it's changed or not today. It was a happy atmosphere that they tried to create."

### 4) *Quality of donor - recipient relationship.*

Reza said, "...we are more closer than before. I mean obviously we are family from a different country and we are close to each other and it doesn't make any difference to us whether we don't give the kidney or give the kidney, we stay close, love each other very much. Just one thing Hassan doesn't drink and now he starts I don't know why maybe my kidney! It doesn't make any difference to us (donating the kidney in our relationship)."

Hassan speaking of his relationship with Reza says, "I hadn't seen him for 8 years before the transplant but we are close. It's been an experience for the whole family I think - it's made us more aware of each other than before. Everybody went for blood tests, everybody was happy to do it (offer to be a donor) - shows me how much they care for me - that's the ultimate test isn't it!"

### 5) *Quality of life.*

No concerns expressed by Reza. Hassan says he has recently had a stomach ulcer for the first time. He takes herbal treatments to deal with some of the side effects of the immunosuppressive drugs. The kidney is still functioning well.

### 6) *Other aspects.*

I asked, "were there any difficulties financially? Did you have to pay for your trip over and everything else?" Reza responded, "oh yes I did, I did. I mean I don't mind." "Was that quite difficult financially?" I continued. Reza explained, "well at that time I was just starting working... but it wasn't hard. I did love to do it but whether you like it or not it's something to do in our family - in our tradition."

Hassan found that financial help was not available and said, "that's part of what affected my decision originally (not to have a living donor transplant at that stage)." I asked Hassan whether Reza had had any financial difficulties he responded, "well when he came he stayed with us and then it became dangerous for him to go back so he stayed with us. We had some monies so we could manage." [from the ensuing conversation it was clear that they worked quite interdependently helping each other out with money working as an extended family].

I asked, "how was it with the culture and religion - attitudes toward transplant?" Reza responds, "well I was born a Muslim but I'm not quite in the way the Muslim people are I don't go to the mosque I don't pray - I don't do all these rules - in the Islam way you must do in the way to help them (people) whether you give them money or food or part of your body. There's no problem on that (being a living donor). They might come and encourage you to do it."

Reza recommends family living donors because he thinks they have good results but he also thinks that outside the family is o.k. Hassan would not put any restriction of which classes of person could donate.

## Interview 8 and 9.

### 1) *Quality of decision making.*

The recipient, Andrew, was at the time of the donation a minor. The family all knew of the kidney trouble for a long time. Colin, the donor, is Andrew's father. He says that he, "had little fear about taking on the operation, only a little apprehension beforehand." He explains that he knew that donation carried a risk but added that he, "wasn't really worried about that." He did not go into further detail. Colin adds that Andrew might have to wait a long time for a cadaver.



Andrew said that his father had decided, "off his own bat" to donate - probably because "he cared a lot for all of the kids."

*2) Feelings after the donation.*

Andrew explains that he wasn't sure why he decided to donate but felt good about his decision.

*3) Quality of care.*

Colin said he was, "very satisfied" with the quality of care at Leicester and both he and Andrew remarked how much cleaner the hospital here was than those in London. Andrew said that there were, "no problems with care on the ward" and that he was "very happy with it." He got worried though when he was called to the operating theatre at 3p.m. when his father had been called at 2 p.m. He was worried that something had gone wrong for his father. (Note: this was some problem in communication, that he was unaware that the operations would be back to back not simultaneous).

*4) Quality of donor - recipient relationship.*

Colin feels that he has always been close with all his kids though he thought that this experience had brought he and Andrew "a little closer." Andrew expressed that he also felt a little closer.

*5) Quality of life.*

Andrew said that he was not suffering "many" side effects - the main one being hair growth. He is taking cyclosporine, aziathioprine and antibiotics. He felt that he was leading pretty much a normal life now.

*6) Other aspects.*

Colin said he had not been greatly affected financially because he still got his basic pay as a postman. Andrew said that he did not like the idea of buying and selling of organs as it might lead to queue jumping which he said was "unfair."

## **Interview 10 and 11**

The recipient, Andrea, was a minor at the time of the transplant and still is now. The donor, Julie, is her mother. I interview them together.

*1) Quality of decision making.*

Julie says that her daughter's kidney was deteriorating and the doctors had said there was nothing they could do and she'd live between 3 and 12 months. When I asked Julie if she had considered the cadaver option she just replied, "I didn't want to do that." Julie feels that they were not told about all the side effects she mentions especially moon face.

*2) Feelings after the donation.*

Julie feels that the good sides outweigh the bad sides.

*3) Quality of care.*

Andrea says that since the operation things have been fine with the hospital and Julie says that she feels that, "the doctors have generally been marvellous."

*4) Quality of donor - recipient relationship.*

Nothing is expressed, however there seems to have been some conflict or stress between the parents before the operation, Julie says that since the operation she feels closer to her husband.

*5) Quality of life.*

Julie mentions moon face and hair growth as two of the side effects. She says that her scar has healed well, she hasn't felt any problems from the operation and has been more concerned for her daughter. Andrea has to shave again. She had stopped growing for a time before the operation and has now started again.

*6) Other aspects.*

No other comments.

## **Interview 12 and 13.**

The donor, David, and recipient, Anne, are brother and sister.

*1) Quality of decision making.*



David describes the extent of Anne's illness and says, "It started really that my dad was going to offer his and I've always been terrified of anything to do with hospitals... but without any hesitation I put my name forward as well and it went from there. Obviously they went for me first because of me being a lot younger than me dad - me dad was only a last resort because of his age.... I had time off work - going backwards and forwards from the hospital, luckily I got time off work I never stopped and thought if they had said no. Alright I know she wouldn't have been able to survive without one but obviously I had a family and I had 3 little girls. Well I suppose if it comes to it me family comes first it's got to be you know - it wouldn't have been the right thing to do and it'd be on my conscience whichever way." Later he says, "really, the operation once I'd made my mind up I didn't worry about it at all... I suppose the last 2 or 3 hours before the operation I did start to worry a bit."

David then goes into a recurrent theme of the interview which was his worry and concern that he would not get paid for his time off work and would be left short. "Luckily" he says he got full pay in the end and got insurance money to cover the mortgage as well, "but it could have gone the other way because me firm wasn't forced to pay me any money." He continues, "the main worry was I got no help from anybody, no advice no nothing. I think you know somebody could have done something for us. The hospital said they were going to and then didn't do a damn thing. They never did get back to me (after I'd asked them about compensation) all they seemed to be concerned with was getting me in their and getting my kidney. Apart from that the way they looked after you was first class, no complaints apart from they didn't seem to take no interest apart from getting you in and getting your kidney." I respond, "so you didn't worry about what was going to happen technically but...?" David replies, "no because they told me you can function just as well on one as you can two... it was a bit - worry over money."

Later David adds, "the persons who said they were going to help on the financial side .. didn't get back to me. Doctors and nurses were o.k. when I was there but they never made no effort - it can be offputting. I was lucky but if it wasn't for work being as good as they were and me being lucky - you don't get no social security or anything like that because it's self inflicted (social security is available but obviously he wasn't aware). Anybody else it could have put them off doing it. I think it would have done me at a different time.. When they ask people to donate to me they ought to have an adviser there because there's certainly nobody outside to help." David later adds that he had lost a promotion at work because the hospital had not organized any early date despite being specifically asked to.

David also later speaks of his sister's husband who wouldn't donate, "alright he's terrified of hospitals but I don't see how he can be any more terrified than me - he said point blank that he wasn't going to give her a kidney. Well that didn't go down too well with me." I respond softly, "you felt angry did you?" David says, "I did - it's his flipping wife! I thought it was right selfish of him as far as I was concerned - his whole attitude."

In some sense it could be said the donor had been cornered into doing something that he felt it was someone else's responsibility to do but although he had negative feelings he also had positive one's. The interview with Helen, the recipient, yielded some interesting information on this point. She was uncertain whether the donor had in fact donated freely. She also said she was no longer motivated to have sexual relations with her husband which she attributed to the fact of donation. However it could be that his failure to offer to donate was what was really putting her off in terms of that failure perhaps indicating to her a lack of love. The interview with her intimated some unexpressed anger toward him and coldness emanating from this. Her choice not to engage in sexual relations seemed to be a point blank refusal based on deteriorated relationship rather than any physiologically (transplant) influenced lessening of sexual desire [although this may also have been present].

Helen also discussed the problems she now had with her eyes and felt that she had not been told that problems with her sight could increase as a consequence of the operation.

## *2) Feelings after the donation.*

I asked David, "do you feel good about your decision?" He replies, "well yes because they might not have got her one in time otherwise - she could have been gone by now, it was as bad as that really, but now she's going to be around for 7 years or so."

The recipient had a worsening sight condition after the operation which she attributed to the transplant and felt that she had not been sufficiently informed about beforehand as a possibility. She had a diabetes condition which appeared to connect into the eye condition. There was clear evidence that she was fairly depressed in some ways and it did not appear that she was enjoying her life much in terms of the strained relationships with family and the very bad sight.



### 3) *Quality of care.*

Both donor and recipient were generally happy with the quality of care.

### 4) *Quality of donor recipient relationship.*

I asked David, "I was wondering has it changed your relationship with your family and your sister?" David replies, "we've been a close family - it probably made a difference with my sister. She was showering me - she thinks she owes me now but as far as I am concerned she doesn't owe me nothing. She doesn't owe me a thing." I continued, "how does it feel when she goes around getting things for you?" David, "well she doesn't now but she brought a few expensive pieces. There's no need - I felt as if, well in a way guilty. She's my sister, she's family. I would have done it for anybody in the family - you would, everybody would."

### 5) *Quality of life.*

David took only one week to get out of hospital. he describes the only problem with his health as, "I feel the cold more.. I got septic a lot - working with meat - never went septic before the operation - somehow the slightest scratch and I go septic. At one stage at work I had seven fingers go septic. I kept going back and I rang up Leicester and had some tests at Boston and they couldn't find nothing wrong anyway I found out what it was in the end - the glands. Apart from that no after effects no side effects, no nothing." Later David adds, "as far as the operation goes I didn't realize a big operation could be so simple. To me I was just so surprised - going into the hospital, waking up after the operation and within about 24 hours I was out and about walking - if I had 3 kidneys and had to do it again I would do."

David says of his sister, "she's a lot more mobile, she's a lot more healthier. She lost her eyesight through it though (can see only about 25% now) but she's had problems with her eyesight for a few years now. She is virtually blind, she can see day from night and can read when things are right close up to her. She has her good days and her bad. She's been told it will never come back. They don't think it will deteriorate any more." (she has diabetes and both eye and pancreatic problems are connected with that.)

Despite these suggested improvements it appeared that the recipient was in a state of depression: and that whatever the improvements in her life they were all relative and the overwhelming impression was that she was not enjoying her life.

### 6) *Other aspects.*

No cultural or religious difficulties with the idea of donation for David. He basically does not agree with buying and selling but adds that everybody has their price and it depends on your situation.

## Interview 14.

Interview with Sandra whose donor father is abroad and could not be interviewed.

### 1) *Quality of decision making.*

Sandra was only dialysing for 3 weeks before the operation. I ask, "did your father just offer immediately?" She replies, "yes, he did." I continued, "how do you sort of feel about his decision?" Sandra responded, "I didn't really think about it at the time it was as if I didn't have a choice in the matter. I mean I always accepted my father's word - that was part of our family and umm.. it was only after the operation that I realized what he'd been through. I mean it was just one of those things he had to do and that was it. No questions asked." I asked, "did he seem to do it automatically or..." Sandra confirms, "yes, yes... I was his one and only child and that was it. He wanted to see me around a bit longer (she laughs.)." I questioned, "did you discuss at all, with the doctors or your father, having a kidney from a cadaver?" Sandra said, "no, not at all - I think because all the tests my father was going through everything was looking alright, we never even touched upon it."

I asked, "what did they explain to you about what was involved with the operation - was it a set of things they explained about risks and benefits, what might happen?" Sandra responded, "just before Dr.. was explaining to me how much better I'd be and all that and yes he did mention that if anything went wrong it would be my father that they helped to keep alive - they wouldn't jeopardize his life. No they didn't go into too much detail on that score - not really. I know they did with my father - he had a good talking to and said, 'don't say anymore it'll put me off - if it happens it happens that's it.' That's the way I felt as well." I responded, "did they say anything about the drugs at all - about any side effects." Sandra responds "no" and says that she had weight problems with the steroids and regaining her appetite post - transplant. She adds that she would have liked to have had some kind of exercise routine and physiotherapy.



An alternative living donor could have been Sandra's mother but she did not seem to be tested or seriously considered. Later in the interview Sandra says that she thinks her mother would not have been able to cope with being a donor. Sandra has no brothers or sisters.

## 2) *Feelings after the donation.*

Nothing to add.

## 3) *Quality of care.*

I asked, "how did you find the doctors and the nurses and the medical care?" Sandra responded, "oh the medical care was wonderful. I mean often when you are in hospital you do get your up's and down's .. they all expected it, they were all very good." Was it quite a relaxed atmosphere?" I inquired. Sandra said, "yes I was in a room of my own and I felt it was my own little world."

## 4) *Quality of donor recipient relationship.*

I asked, "was it strange the idea of having someone else's kidney - how did it feel?" Sandra said, "no, that didn't enter my mind at all. I suppose it was something I needed to get well and be well and I never gave that a second thought." I continued, "do you think that it was strange when you reflect back?" Sandra responded, "uhum, yes really - perhaps if it hadn't been my dad - if it had been an unknown perhaps I would have thought about it more. It would certainly feel foreign then wouldn't it!" Sandra later says that she feels a lot closer to her father since the operation and thinks that is partly through the experience they have gone through together.

Sandra described there being stresses and strains with her own family - she had continued to work full time and was very tired each evening when she got home from work and just wanted to flop down on the sofa and watch T.V. "a man is different yes you can work full time - you don't have to come home and do all the housework and start again you know" I replied, "so you had 2 full time jobs!" Sandra agreed, "ooh yeh, it was hard going," and added that they would have been in financial difficulty had one of them stopped working.

## 5) *Quality of life.*

Sandra said that the operation went "smoothly." She describes problems of weight which she says have remained. Sandra says that she values life more and feels that she definitely has a better quality of life.

## 6) *Other aspects.*

I asked, "did it affect you financially at the time or your father?" Sandra answered no with regard to her father and continued, "I've been with the bank 10 years so I was entitled to 6 months sick leave with full pay so there was no real problem."

Sandra talked of there being "so much renal failure about these days. I don't know why; is it because we have got a different diet these days? (she asked rhetorically)"

She adds that she wouldn't personally have taken a kidney from a friend, "if anything happened to them I'd feel so guilty."

She feels that doctors should decide transplant policy but that where money is involved there should be restrictions.

## Interview 15 and 16.

In this instance the donor and recipient both came to the interview with their partner. Mark the donor came with his wife Helen. John the recipient comes with his wife Karen.

## 1) *Quality of decision making.*

Mark said, "there was a possibility that we'd be compatible. Basically thought that it was a good idea, went through all the procedures to get checked out and that's it really. We discussed it between ourselves to see what we should do (he says turning to his wife)." I asked, "were you worried?" Mark replied, "no, it's fair to say I wasn't worried at all - I had total belief in the fact that doctors wouldn't entertain it unless there was a good chance, and that they wouldn't do anything to me that they'd feel I couldn't cope with. I must admit that as it got a bit nearer me wife was feeling a bit worried - it was a lot harder for her." Helen comes in at this point saying, "I think what made it hard for us was that the hospital is 79 miles away - we had to come and stay in a hotel (she and John's wife) there were no facilities for us to stay."



Mark says that one of his two brothers had children which was a factor in them not donating. (Note: I am not clear why the other brother did not seem to be involved. Certainly however Mark and John look almost like twins and were probably the best match.)

Mark added that he felt the hospital had explained to him about the time he may have to take off work after the operation. I continued, "what did you understand about the risks involved, what was told to you?" He replied, "I do believe the doctors really tried to make you aware - I wouldn't say they tried to put you off but all the way through the tests it was pointed out to you what you were doing."

John says that he was on dialysis for about 2 months and during this time Mark was having blood tests for donation purposes. John said that the decision came from Mark himself, "I was on dialysis and Mark said I could have one of his kidneys." I asked, "did you consider the idea of a cadaver?" John responded, "well I don't think it came into it - I would have had one. With Mark offering me his kidney it gave me a chance to have a better life sooner sort of thing rather than waiting 3 or 4 years maybe for another one."

John said of the hospital staff, "if you ask questions they'll always tell you - they've always got time for you - you can phone them up and they say if you don't think your right come in." His wife adds, "the only complaint I've got about the whole thing - you only get a bit of paper and you read it and they tell you so much don't they - but you have said since that there's a lot of things that if you had known you would have never maybe gone for it - but there again you had your ups and downs didn't you." John continues, "trouble is they get you in and boost you up and say here's the kidney - and we thought 'that'll be alright' then you have the transplant and like you say it get's punctured - why did it happen to me sort of thing when they said the kidney was a good kidney. They didn't know why the kidney ruptured anyway."

## *2) Feelings after the donation.*

Mark said it was a bit of a shock when John's new kidney ruptured and he was "upset" but later he adds that put in the same situation again he would donate again. He feels that people made quite a fuss over him and adds that he thinks most people in his position would do the same thing. He is not sure whether he would have given a kidney to a stranger though.

## *3) Quality of care.*

Mark feels that the atmosphere was very personal in the renal unit and says that the doctors and nurses were "very good" I asked John, "how did you find all the doctors and nurses on the ward?" He replied, "oh they were brilliant, we couldn't wish anything better." John's wife adds, "even me who was not a patient - they didn't leave you out and it was just as if you were in a family, so friendly."

## *4) Quality of donor recipient relationship.*

Mark feels that there's not much change in his relationship with John then adds, "I do feel that we are slightly further apart - not to any effect really - not that we've got problems. I'm still closer to him than the other two brothers."

John feels that there has been no change in his relationship with Mark. John's wife adds that since having Mark's kidney John has a cup of coffee now and again which he never used to.

## *5) Quality of life.*

Mark describes still having, "partial rashes along the scar and I get a twinge. I was a bit sore for a while."

John speaks of 2 rejection episodes the first of which he was in hospital 6 weeks for the second 11 days. The first time his kidney was quarterized and he lost around a third of it. Of the drugs John says, "I got a side reaction but as soon as they started lowering the cyclosporine it went away" he also says his hands may be getting colder than usual in response to me asking if azathioprine had been having any effect.

John is now working as a full time houseworker and adds about paid work that he couldn't do it full time at least, "not at the job I was doing which was a fence erector which was fairly physical." He later adds, "I think the ruptured kidney did me more than anything confidence wise I think for a start you've always got that thing in the back of your mind if there's a twinge in your side. If nothing had happened to the kidney when I first got it I might be in a better frame of mind." His wife adds, "since you've had this operation our sex life has gone to zilch because you've lost all - you don't have a great deal of feeling do you." John says, "umm." She continues, "and all these little things ought to be pointed out so that when they come it's not a frightening thing - oh no why have you lost your sex drive - that causes more of a problem. We can't do anything about that we just struggle on don't we. I mean we don't care about that but some people might. I think you've got to know the in's and out's, counsel like the donor or the



recipient and the family - like his father is a born worrier .. he's an epileptic and he really went hot over it.. If we mention the thoughts of John going back to work I think he'd have a lairy fit. He thinks John has had something big. I do think counselling would be a good thing... all the way through."

[Note: loss of sexual desire may have been a purely physiological consequence of the operation but may alternatively have been a consequence of change in the psychology of the relationship between the recipient and his wife. The swapping of job roles with him now doing domestic duties may have been experienced by him as emasculation. There is in reality nothing intrinsically emasculating about this change of roles but it can be experienced this way influenced by societal pressure in this direction. Additionally she appeared domineering of him in the interview and even 'putting him down.' This could even more be experienced as emasculation with diminution of sexual desire through repression of feelings such as anger towards her about being treated that way, a feeling of ineptness and low self-esteem through not being able to fully stand up for himself at this time].

Although John feels he's been up and down about having a transplant he now feels happy. His wife says, "transplants are brilliant."

#### 6) Other aspects.

Mark said that it had been hard financially for John and his wife. John in his interview also says this and adds that he and his wife have swapped roles with her now being the main "breadwinner" and him doing the housework. Both John and his wife are against the buying and selling of organs - John says, "that's going too far."

### Interview 17 and 18

James received an organ from his sister Melanie.

#### 1) Quality of decision making.

James, the recipient, describes how it was difficult for him and his family to cope while he had all the health problems, "I did miss out a lot on one of my daughters being a child." "It's been a strain on my family, before the transplant I came in because I couldn't stop being sick and that was probably the worst time. I was trying to keep it down and all they were doing was trying to inject people which didn't do any good at all. The doctors seemed to have no time for me. I also feel that that's wrong today. I felt that when I came to the clinic you got to know one doctor and all of a sudden he'd gone and a new doctor came along and he knew nothing about you and every time I felt I had to impress on the new doctor my capabilities of doing things. You had to get the message over again, again and again. That could be improved upon..... I'm one of those people who likes to ask questions, it was frustrating. There was only one doctor who didn't talk down to you. They don't explain - sometimes you are left in the dark."

Melanie expressed that she was "happy with her decision" and did not feel obligated to donate but did it because she wanted to. She was in general very satisfied with the quality of information and communication. She had donated because she wanted to help him out of his situation.

#### 2) Feelings after the donation.

Melanie was somewhat concerned after getting pregnant shortly after the donation but this did not present a problem in practice.

#### 3) Quality of care.

Melanie was happy with the quality of care. James expressed concerns about the attitudes of medical staff on the ward.

#### 4) Quality of donor recipient relationship.

James says, "I've never been close to my sister. I don't go and see her now. The main reason is that her husband smokes.... I feel as though I owe her a great debt but I don't have to repay it. I can't get near to her because of the smoking - I can't put up with that. Can't be in the same room. I go and see them now and again. They don't smoke in my company." James "doesn't know" why his sister donated - "she never told me" "I'd love to be closer to her" he adds. Melanie was concerned about James, feeling that he had got more "uptight" about things and somewhat fanatical. There was friction about the smoking.

#### 5) Quality of life.

James said, "after the transplant I felt well straightaway." Later he talks about feeling he has depression saying he doesn't, "know the reasons for it.... I have no time to myself - whether that is causing my depression I don't know. Thing is you know your depressed but you can't do anything about it - or you don't



want to." He connects it with the fact that he is taking drugs which involve suppression of his immune system, "that's one thing I can't understand I've been given a new life but I'm not happy. The reason I think it's the tablets is that I can be in the shop one day and I can be on such a high and I can joke and this that and the other. From being on such a high for half a day I'm right down a gravel pit - real mood swings. That's the side I don't like because the highs don't last long enough. So really the depressions are more and more frequent and it's becoming more long term. The other side of it is that when you are in hospital you're here so often with one thing or another with dialysis and now I don't feel a part of it anymore. When you are in hospital you are like part of a large family but I now feel cut off from it. You don't feel part of the place anymore and you lose contact with patients. I do feel doctors haven't got enough time for you. It's not the patients problem that the doctor has only got 5 minutes for you. That's got to be sorted. The biggest fear is that if ever my transplant packs up what do I do?" Apart from these more psychologically oriented aspects of health James says, "I've been very well so far."

Melanie did not express any problems with her physical health in connection with the donation.

#### *6) Other aspects.*

Nothing added.

### Interview 19 and 20

#### *1) Quality of Decision Making.*

The recipient Mick was 17 years old and started feeling rough all the time. Problems started from there with diagnosis of kidney disease. The transplant has lasted for 7 years. He felt that they had been told about risks including the possible side effects of drugs.

Jim the donor (Mick's father) likened donation to something instinctive "it was like if you had a child that was drowning you'd jump in to save them even if you couldn't swim." He had made the decision almost immediately. (This doesn't take into account the possibility of cadaveric "life savers" however, although it must be added that the recipient was young and had already been on the waiting list for 18 months). The donor said he hadn't been concerned about the risks "only about helping (the recipient) get right."

#### *2) Feelings after the Donation.*

The donor's recovery involved only a 7 day stay in the hospital after donation.

#### *3) Quality of Care.*

Both felt it was like being in "a big family." The quality of care was "A1..like a hotel."

#### *4) Quality of Donor Recipient Relationship.*

Both said their relationship was unaffected by the donation, although the donor's wife had worried about the donation.

#### *5) Quality of Life*

No problems were detailed by the donor. The recipient had had a rejection crisis and although it was a good match the expectancy of graft survival was down because the kidney had black spots on it which the doctors said were related to the recipient smoking. The recipient noted the fact that 20 years previously he would have died.

#### *6) Other aspects.*

Both the donor and recipient were opposed to the idea of commercialization because it could be exploitative. The recipient had hallucinations which he found like near death experiences. He had seen an angel come down and had felt that the T.V. was on when it wasn't and was able to predict exactly what was going to come on T.V. next. He had found this experience frightening and had tried to tell himself to "snap out of it"

### Interview 21 and 22

#### *1) Quality of Donor Recipient Relationship.*

Mark, the recipient, had Allports Syndrome leading to renal failure which precluded his brother from donating as he had it also. The donor, John, was the recipient's father. He had actually approached the hospital about the possibility of living donation. The recipient's mother had pulled out of the tests. No reason was given. The recipient's brother was coping far better with CAPD which was the reason why the recipient was chosen to receive the living donor organ. That decision was actually taken by the recipient's brother. It was a fairly major discussion in the family. "The risk part to me was paramount, to me I can understand his feeling of wanting to help his sons and I didn't want that to jeopardize his life by really being selfish as I saw it by taking that kidney. We'd been on the waiting list for 18 months. The decision was really taken by my father and



The recipient was out of the hospital 14 days after the operation and at work within 10 weeks. He describes his health as fantastic. The change was miraculous. The recipient fears that the transplant will not last and hopes that medical technology has further advanced by the time it does, so that there will be an alternative. He gets concerned when there are twinges.

*6) Other Aspects.*

There were financial concerns at the time relating to taking time off work. The donor-father was back working fairly shortly after the operation however. He ran a pub which put a pressure on his wife because she had to look after everything for a while. The recipient added that this had a positive effect of accelerating his parents giving up the pub which they had intended to anyway. The recipient and his brother were "fortunate" to be working for good companies where their pay was not affected. He didn't expect the hospital to help out financially and said if he had needed financial support that would be the role of social security. The recipient paid for extra staff to cover at his parent's pub during the period of illness.

Recipient feels LDT is a good thing provided it doesn't put the donor at risk. Doesn't agree with recipient giving money to the donor because it affects judgment when money comes into the equation but he feels it is o.k if the recipient wants to reward the donor in some way - it should totally be the choice of the recipient.



brother because at the time they recognized that I was in greater need." This also related to it being easier for the recipients brother to continue jobwise. His concerns about the process related to the fact that donor nephrectomy was a complicated procedure, more so than the operation was for the recipient. "Anybody having surgery voluntarily is an idiot basically (laughing)! but I can recognize why he did it."

The recipient didn't feel donation involved a debt when it was done between family and knew his father didn't see it that way "in some ways he's glad to have the opportunity to prove his love." The recipient feels "gratitude..respect.. but not debt."

The recipient said that he asked the doctors about the risks but their response was minimal. He felt that if they had said any more it would have warned him off. He thought that there was never any way any kind of ethical doctor would do that operation if there was any risk. "So really the doctor's being the expert, saying it was a safe operation then my faith was in them. Medically the doctors had said we could withstand that operation and their was minimal risk and so I had every confidence in them....He's come through it with no problems at all."

The donor recounted the same story and then spoke of his motivation for donation "when I first volunteered for transplant I had two long interviews ..the first two he was making quite sure I was absolutely serious about it before he went to stage 3. When it got to stage 3 he said 'well fine we'll go ahead but whose to have the kidney ..and I said well surely that's a medical decision for you not for me but I think (the final recipient) is the most ill and we discussed it at home and (the cadaver recipient) said (the living donor recipient) is quite ill and should have the kidney...Then I had a final interview with... who explained all the surgical circumstances risks whatever and explained the same thing to the recipient...It was explained what was going to happen.. They went to a great deal of trouble to ensure I knew what was going to happen and I felt quite happy about that...I thought there approach was extremely good..I had absolutely no inhibitions about it at all..The only inhibitions as far as (my son the recipient) was concerned was the physical aspect of the surgery he just doesn't like knives. I had a problem in the surgery apparently. I was warned about this that I had a short jaw and a narrow throat and they might have a problem but they'd get over that. Apparently I nearly didn't ..once they switched the ventilating system off I didn't start breathing again.. I was in intensive care for 24 hours apparently but it didn't have an effect on me .. I was up and about in a couple of days.

## *2) Feelings after the donation.*

Nothing to add.

## *3) Quality of care.*

The recipient felt that they hadn't done a very good job with his brother. He feels the hospital don't manage very well when something is going wrong "the hospital don't seem to want to get involved... In cases like my brother he needs one to one attention..at the moment it's the hospital versus him and it shouldn't be that way. He's got to have an ally in hospital that he can say to 'look I'm just not happy' - someone that'll take things up on his behalf." He sees a conflict of interest between the business side of the hospital and the caring for people side "the only thing a patient can do is to kick up a fuss and make a nuisance of themselves.. that's the only way that he and I feel we can get what we want."

The donor also commented that while one or two doctors were very responsive others were not. He commented that there was no drive on the ward with it just seeming to be an apathetic waiting period for transplant. He says with regard to his son receiving a cadaveric organ that he has "a very very severe criticism..he had gone in for a check-up after saying things were wrong and the doctor didn't do anything about it..it annoyed me..the nurse said I'll see you in three weeks time..I said 'you can't leave him for three weeks without some attention and monitoring it's ridiculous and she more or less said well that's the system. So we waited and he was quite ill over christmas and we brought him in.. he saw one doctor who said it was depression at that time he'd lost nearly another stone at home...Took him home on the Friday and on the Monday he looked that bad that we called the local doctor and he said 'well he's obviously very ill' so he rang the hospital and arranged for him, to come in on the tuesday ..we brought him in at 11 and he could hardly stand and this is the big criticism I've got we went to the reception area and the sister said go back to the waiting room and he could hardly stand so I went to the waiting room and I said well I'm not waiting any longer..and .. came and said what on earth is the matter and I said 'we've been waiting nearly an hour now and look at him so she immediately took him into her room.. and fetched the nurse and this little nurse I'm sure she saved his life she looked at him ...(and found) he'd been on the wrong bags (for dialysis) for a fortnight...and the doctor who had seen him previously had said it was depression!

## *4) Quality of Donor Recipient Relationship.*

Nothing to add.

## *5) Quality of Life*



## **Appendix 3: EUROTOLD Professional Questionnaire Materials.**

This appendix provides copies of the 2 major EUROTOLD professional questionnaires discussed in chapter 9 of the PhD and a full copy of the results relating to them.

### **3A: Questionnaires.**

#### **3A(i): Attitudes Questionnaire**

(spaces for answers have been condensed question 13 considering clinical matters is omitted).

1. A 55 year old patient is brought to your clinic to discuss living donor transplantation. He has been on dialysis for 2 years and has not been offered a cadaver kidney. He has no suitable family donors but he brings with him a 40 year old friend who has offered to donate a kidney.  
Would you:
  - (a) tissue type and investigate the potential donor ☐
  - (b) refuse to consider the transplant ☐
  
2. A 50 year old Asian man with diabetic renal failure has been on dialysis for 5 years and is starting to get retinopathy. He has not been offered a cadaver kidney. He has no suitable or willing donors in his immediate family. He wants to go to India to have a kidney from an unrelated donor.  
Should you:
  - (a) let him go ☐
  - (b) offer him a blood group compatible cadaver kidney ☐
  - (c) leave him on the waiting list ☐
  
3. A 36 year old patient with chronic renal failure treated by haemodialysis for 2 years. Assuming comparably matched kidneys the ideal donor would be:
  - (a) cadaver ☐
  - (b) living related donor ☐
  
4. A 45 year old female with chronic renal failure (very recently diagnosed) attends at your centre with her 50 year old brother who is prepared to donate one of his kidneys to her. He is a 6 antigen match. There is currently no good matched cadaver kidney available.  
Would you
  - (a) accept the brother now as a donor ☐
  - (b) wait for a cadaver kidney to become available. ☐

If you answered (b) to the above, please answer the following question.

How long would you wait for a well matched cadaver kidney before using the brother as a living donor?

  - (a) One year ☐
  - (b) Two years ☐
  - (c) Three years ☐



- (d) Four years ☐
- (e) Five years ☐
- (f) Longer ☐
5. A 20 year old student is about to start University when he is diagnosed as having renal failure. His creatinine is 500 and he will need to start dialysis in about 6 months. His parents both offer to donate kidney. His mother is a 4 antigen match and his father is medically unfit due to hypertension.
- Would you:
- (a) transplant the mothers kidney prior to starting dialysis ☐
- (b) wait until he had been on the cadaver list for 6 months before considering a parent donor ☐
- (c) wait 2 years on dialysis before considering a parent donor ☐
6. A 70 year old female with ESRF is having difficulty coping with CAPD. She has good cardiac function and is not sensitised. Her 75 year old husband is blood group compatible and offers to donate a kidney. The patients 50 year old daughter also offers to donate a kidney, she is a 4 antigen match but has a resting BP of 150/90.
- Would you accept:
- (a) the spouse donor ☐
- (b) the daughter as donor after antihypertensive treatment ☐
- (c) reject both living donors and leave on the cadaver waiting list ☐
7. A 14 year old boy has been on haemodialysis for 3 years but is experiencing severe psychological problems with needling. He is unsuitable for CAPD as a result of previous urological surgery as an infant. His mother is a single parent with three other children, one of them being his identical twin. The patient reacts strongly to mother on cytotoxic cross match as a result of previous transfusion.
- Would you:
- (a) transplant a kidney from the twin ☐
- (b) await a good cadaver match ☐
- (c) await a blood group compatible cadaver graft. ☐
8. A 40 year old builder is about to start dialysis. His two brothers offer to donate a kidney. Both are equally matched.
- Which of the two would you favour:
- (a) Brother aged 38, unmarried and longterm unemployed ☐
- (b) Brother aged 56, married with 2 children and in employment ☐
9. A 20 year old man has been on dialysis for three years and is not coping well. His only living relative is his mother who is willing to donate but has diet controlled diabetes. Would you:
- (a) accept the maternal donor kidney ☐



(b) leave the patient on the cadaver waiting list

☐

10. A 37 year old male with diabetic renal failure has been on dialysis for 5 years and is starting to get retinopathy. He has a brother who is a 3 antigen match. There are no other suitable family donors apart from his father who is aged 55 and a 3 antigen match.

Would you

(a) transplant the brother's kidney

☐

(b) transplant the father's kidney

☐

(c) leave on the cadaver waiting list

☐

11. A 45 year old female has been on dialysis for 2 years without an offer of a cadaver kidney. The following are all willing living donors please rank the potential donors in order of preference.

(a) Daughter age 25 with a 4 antigen match

(b) Husband (40 year old) who is blood group compatible only

(c) Sister with 3 dependent children and a 4 antigen match

1st choice ☐

2nd choice ☐

3rd choice ☐

Leave on the cadaver waiting list ☐

12. A 36 year old female patient with 3 children aged 18, 10 and 8 is having difficulty coping with regular haemodialysis. Her husband, eldest child and sister are all willing potential donors, please rank these potential in order of preference.

(a) Her husband aged 38. He is a fit self-employed builder and is blood group compatible with wife.

(b) Her 18 year old son is well and is a 4 antigen match.

(c) Her sister is a 6 antigen match but has 4 dependent children and is recently divorced.

1st choice ☐

2nd choice ☐

3rd choice ☐

Leave on the cadaver waiting list ☐



**3A(ii): Transplant Centre Questionnaire**  
**(spaces for answers have been condensed)**

Please indicate your speciality and grade:

Surgery ☐ Nephrology ☐ Anaesthesia ☐

Other speciality \_\_\_\_\_

Consultant ☐

Senior Registrar ☐

Registrar ☐

Junior Doctor ☐

Nurse ☐ Grade \_\_\_\_\_

This questionnaire has been designed by the EUROTOLD project to gain background information about transplant centres.

Your responses are entirely confidential and you will not be required to identify yourself by name.

This questionnaire is being administered in many hospitals both in the UK and continental Europe, the results will be available towards the end of the project in December 1995.

If you have any questions about this questionnaire or about the project in general please contact the Secretariat

Our NEW telephone and fax numbers are:

Tel. +44 116 258 8080

Fax. +44 116 249 0064

**For Office use only**

Centre Code:

1. What is the catchment population (in millions) of your local renal transplant centre? \_\_\_\_\_
2. How many patients do you currently have on you transplant waiting list? \_\_\_\_\_
3. When did your unit first perform cadaver kidney transplants? \_\_\_\_\_
4. How many cadaver kidney transplants has your unit performed since the programme started? \_\_\_\_\_
5. How many cadaver kidney transplants did the unit perform in 1993? \_\_\_\_\_  
1994 \_\_\_\_\_
6. What was your transplant rate per million population in 1993? \_\_\_\_\_ 1994 \_\_\_\_\_
7. Do you have a living donor transplant programme?



Yes ☐

When did your unit first perform a living donor kidney transplant?

How many living donor kidney transplants have you performed in total? \_\_\_\_\_

How many living donor transplants did you perform in 1993? \_\_\_\_\_

1994? \_\_\_\_\_

No ☐

8. If the answer to question 7 is no, have you had one in the past?

No ☐ Yes ☐ why has it been discontinued? \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

9. Do you foresee the expansion of a living donor kidney transplant programme at your centre?

Yes ☐ No ☐ Maybe ☐ Under what circumstances? \_\_\_\_\_

10. Does the law of your country prevent the use of living donors?

Yes ☐ No ☐

11. When do you consider patients for cadaver transplantation?

Before dialysis is needed? ☐

When dialysis is needed? ☐

Only after patient has been on dialysis for a certain length of time? ☐

please specify how long \_\_\_\_\_

**ONLY ANSWER THE FOLLOWING QUESTIONS IF YOU HAVE A LIVING DONOR TRANSPLANT PROGRAMME**

12. Do you have written guidelines on the use of living donors ?

No ☐ Yes ☐ Would it be possible to have a copy?

13. Do you have a written protocol that is used for the evaluation of the donor?

No ☐ Yes ☐ Would it be possible to have a copy?

14. When would you consider the use of a living donor transplant?

Before dialysis is needed? ☐

When dialysis is needed? ☐

When a patient is put on the cadaver transplant waiting list? ☐

Only after patient has been on the waiting list for a certain length of time? ☐

please specify how long \_\_\_\_\_

15 Who would you consider as potential donors?



Parent	<input type="checkbox"/>	Grandparent	<input type="checkbox"/>
Sibling	<input type="checkbox"/>	Son/daughter	<input type="checkbox"/>
Spouse	<input type="checkbox"/>	Friend	<input type="checkbox"/>
Relatives through marriage	<input type="checkbox"/>	Others	<input type="checkbox"/>

please specify \_\_\_\_\_  
\_\_\_\_\_

16. How do you identify prospective donors?

Patient approaches members of their family ☐

Spouse or parent of patient approaches members of the patient's family ☐

Transplant coordinator approaches members of the patient's family ☐

A member of the nephrology staff approaches members of the patient's family ☐

Others please specify ☐

\_\_\_\_\_  
\_\_\_\_\_

17. Who is the primary source of information to donors and recipients about living donor transplantation in your centre?

\_\_\_\_\_

18. Are there any other sources of information available?

\_\_\_\_\_

19. Who discusses with the donor

(a) the potential benefits or alternatives for the recipient

(b) the potential risks involved for the donor?

(a) \_\_\_\_\_  
\_\_\_\_\_

(b) \_\_\_\_\_  
\_\_\_\_\_

20. Are there any other sources of information relating to the items in question 18 available such as leaflets, pamphlets, videos, support groups?

\_\_\_\_\_

21. Are the financial implications discussed with the donor?

Yes ☐ No ☐ By whom? \_\_\_\_\_

22. Is there any financial help available for donors?

No ☐ Yes ☐ Please explain \_\_\_\_\_  
\_\_\_\_\_

**ONCE A PATIENT HAS EXPRESSED A WISH TO CONSIDER A TRANSPLANT FROM A LIVING DONOR WHAT PROTOCOL DO YOU FOLLOW?**

23. Who do you ABO-blood type first, second, third ?



Genetically related family members \_\_\_\_\_ ☐  
Non-genetically related family members \_\_\_\_\_ ☐  
Others please specify who \_\_\_\_\_ ☐  
\_\_\_\_\_

24. Do you tissue type and cross match all prospective donors that have an ABO-blood match?

Yes ☐ No ☐ If no, how do you select donors at this stage?  
\_\_\_\_\_

25. Do you require a minimum level of HLA matching between donor and recipient?

No ☐ Yes ☐ please specify \_\_\_\_\_

26. Could you place a tick against the procedures you routinely give to prospective donors?

- |  |  |
|--|--|
| a. History and physical examination _____ <input type="checkbox"/>   | l. Renal arteriogram _____ <input type="checkbox"/>                                    |
| b. Complete blood count _____ <input type="checkbox"/>   | m. 24 hour urine _____ <input type="checkbox"/>  |
| c. Comprehensive blood chemistry _____ <input type="checkbox"/>  | (Creatinine. Protein. Calcium. Oxalate. Cysteine. Uric acid.)                          |
| (Na. K. Cl. CO <sub>2</sub> . Ca. Blood urea Nitrogen. Creatinine. Cholesterol. Triglyceride. Phosphate. Total bilirubin. Alkaline phosphatase Lactate dehydrogenase Aspartate aminotransferase. Alanine aminotransferase. Uric acid.) | n. Urinalysis by nephrologist _____ <input type="checkbox"/>                           |
| d. Fasting blood sugar _____ <input type="checkbox"/>  | o. Urine culture (if evidence of bacteriuria or pyuria) _____ <input type="checkbox"/> |
| e. Glucose tolerance test _____ <input type="checkbox"/>   | p. Pregnancy test _____ <input type="checkbox"/>                                       |
| f. Haemaglobin A1C _____ <input type="checkbox"/>  | q. Tuberculin skin test _____ <input type="checkbox"/>                                 |
| g. Serological test for syphilis _____ <input type="checkbox"/>  | r. Electrocardiogram _____ <input type="checkbox"/>                                    |
| h. Hepatitis B surface antigen _____ <input type="checkbox"/>  | s. Chest roentgenogram _____ <input type="checkbox"/>                                  |
| i. Hepatitis B surface antibody _____ <input type="checkbox"/>   | t. Urine osmolality _____ <input type="checkbox"/>                                     |
| j. Hepatitis B core antibody _____ <input type="checkbox"/>  | (after overnight thirst)   |
| k. HIV antibody _____ <input type="checkbox"/>   | u. Intravenous pyelogram _____ <input type="checkbox"/>                                |
|  | v. Pelvic examination _____ <input type="checkbox"/>                                   |
|  | w. Stress multigated acquisition scan <input type="checkbox"/>                         |
|  | x. Pulmonary function tests _____ <input type="checkbox"/>                             |

27.If there any other procedures you routinely give to prospective donors? could you list them below?  
\_\_\_\_\_

WHAT ARE YOUR CRITERIA FOR EXCLUDING A DONOR?

28. Age; minimum \_\_\_\_\_  
maximum \_\_\_\_\_

29. Do you try to match the ages of donor and recipient?

No ☐ Yes ☐

If yes what is the maximum age difference you would accept? \_\_\_\_\_

30. Do you exclude donors who require antihypertensive drugs to normalize blood pressure?

Yes ☐ No ☐

31. What is the maximum blood pressure readings at which you would accept donors?

Systolic \_\_\_\_\_ mm Hg Diastolic \_\_\_\_\_ mm Hg

32. Does a family history of hypertension exclude a normotensive donor? Yes ☐ No ☐



33. Does diet controlled diabetes exclude a donor?

Yes☐No☐
34. Does insulin dependent diabetes exclude a donor?

Yes☐No☐
35. Do kidney stones or evidence of kidney stones exclude a donor?

Yes☐No☐
36. What is the minimum serum creatinine concentration at which you would accept a donor?

mg/dL
37. After over-night thirst what minimum level of urine concentration you would accept?

mosm/L
38. Do you exclude donors with unexplained microscopic haematuria?

Yes☐No☐
39. Do you exclude donors with proteinuria?

Yes☐No☐
- If Yes what level of protein do you accept?
40. Obesity ? at what % above ideal body weight would you exclude donors?
41. Does evidence of deep vein thrombophelbitis or thromboembolic disease exclude donors?

Yes☐No☐
42. Do you obtain psychiatric/psychological evaluation for all potential donors?

Yes☐No☐
43. If Yes when?

Before ABO-blood typing☐

Before tissue typing☐

Before donor work up tests☐

After all exclusion criteria have been met☐
44. Is the psychiatric/psychological evaluation of prospective donors undertaken by the recipient's physician?

Yes☐No☐If No, who evaluates the prospective donor?
45. Do you routinely test all potential donors for HIV antibody?

Yes☐No☐If No What specific groups of people do you test?
46. What is the average length of time between a patient first considering a kidney from a living donor and them actually having the operation?



3A(iii): LIVING DONOR HEALTH REGISTRY

ID OF DONOR .....

D D M M Y Y

D D M M

Y Y

Date of Birth: Donor sex: M/FDate of Donation:

Health Insurance ☐

Marital Status:..... Dependent Children

(ages):.....Occupation:.....

Relationship to Recipient: Parent ☐ Sibling ☐ Other ☐ please

specify.....

RELEVANT PAST HISTORY (Please tick)

Hypertension ☐ Smoker ☐ Blood Transfusion ☐ Date.....

Blood Donation ☐ Date.....

Diabetes: Insulin dependent ☐ Diet controlled ☐

Psychological/Psychiatric ☐ Date.....

Specify.....

Counselling

Other

.....

.....

PRE-DONATION STATUS

Blood Group:..... Rh:..... HLA typing

locus:A/B.....DR:.....Other:.....

(subtypes of A if known)

BP lying/standing...../..... Creatinine:.....(mmol/l) Glycosuria ☐ Protein Urea ☐ GFR:

.....

Infection (if present, specify):.....

Virology: CMV +/- ☐ HBs Ag +/- ☐

.....

.....

AT OPERATION (Please tick)

Prophylaxis: Heparin:☐ Antibiotics:☐ Mannitol:☐ Steroids:☐ Others (please

specify):.....

ANATOMICAL DETAILS

Kidney: L/R Incision: Loin/Ventral 12th rib removed: all/part/none Capsular lesion: Yes/No

Vein 1/>1 Artery: 1/>1 Ureter: 1/>1



Bench Surgery ☐ please

specify.....

### POST DONATION STATUS

Post-op complications: Yes/No    Infection: Wound ☐ Chest ☐ Urine ☐

Thromboembolic ☐ Other

.....

**AT TIME OF DISCHARGE**

D D M M Y Y

**Date of Discharge:**

BP lying/standing:...../.....

Creatinine.....mmol/L

### Wound Hernia ☐

Repaired ☐

Date.....

D D M M Y Y

**Date of Death:**

### Cause of

Death.....

Date..... Name.....Transplant

Centre:.....

(Please print)

Mail to:EUROTOLD (LDHR) Department of Surgery, Leicester General Hospital, Leicester, LE5 4PW,  
UK.



.....  
**6. Relationship**

If you have legislation relating to LDT does the law restrict the categories of person who may donate?

Yes ☐  
which of the following categories of person are prevented by law from being donors?

- |                                  |   |                                   |
|----------------------------------|---|-----------------------------------|
| parent <input type="checkbox"/>  | distant relative <input type="checkbox"/> | stranger <input type="checkbox"/> |
| sibling <input type="checkbox"/> | friend <input type="checkbox"/>           | other <input type="checkbox"/>    |
| spouse <input type="checkbox"/>  |   |                                   |

No ☐

**7. Commercialisation**

If you have legislation relating to LDT does the law outlaw commercial trade in organs and tissues?

Yes ☐  
Can you give details?

.....  
No ☐

Is reimbursement of expenses permitted?

Yes ☐  
No ☐

**8. Other**

We would value any other information you have which you feel may benefit this project.



.....  
No ☐

*and*

b) the substance of what information is to be disclosed and by whom

Yes ☐  
Please give details?

..... No ☐

(ii) Whether you have legislation relating to LDT or not is there general legislation, case law or other material relating to the issue of consent to medical treatment particularly in terms of disclosure of information and voluntariness?

Yes ☐  
Can you give details?

.....  
No ☐  
Could you please estimate how the issue of consent for potential donors and recipients might be dealt with in practice if it were a question brought before the courts?

.....  
**Laws relating to capacity to consent are likely to be very relevant to us. Questions 4 and 5 in particular relate to this issue.**

**4. *Minors (children).***

If you have legislation relating to LDT does it provide a minimum age or other criteria concerning young persons as live donors?

Yes ☐  
Can you give details?

.....

No ☐

Whether there are criteria or not and whether you have legislation or not how is the matter of young persons as living donors likely to be dealt with by the courts in practice? For instance what might be the minimum age for a donor that a court might find acceptable, or would this depend on maturity of the individual person at issue?

**5. *Mental Disability.***

If you have legislation relating to LDT does it have provisions concerning persons suffering from mental disability? Can you give details?

If there are no specific provisions in legislation governing this matter how is the matter of persons with mental disability as living donors likely to be dealt with by the courts in practice? For instance would certain restrictions be imposed? Would the court seek to ascertain the feelings of the mentally disabled person? Could donation go ahead against the feelings of the mentally disabled person?



**3A(iv): LEGAL Questionnaire**  
(the spaces between questions have been condensed).

**1. Legislative Provision**

Is there legislation which specifically regulates transplantation and particularly LDT (living donor transplantation in your country)?

Yes ☐

Can we have a translated copy along with other relevant information such as Parliamentary debates and interpretation in the courts in practice?

No ☐

Can you give possible explanations as to why there is not direct legislation of this kind?

.....  
Could you give us details of any professional guidelines, working parties, codes or committees on transplantation which influence or regulate the use of living donors in practice?

.....

**2. Clinical Conditions / Criteria**

If you have legislation relating to LDT does it specify clinical conditions or criteria that must be met for a living donor transplant to proceed? For example:-

- a) It must be the best alternative for the recipient ☐
- b) It is allowed only when there is no appropriate cadaver organ available ☐
- c) It is allowed only where no serious risk to the health of the donor is apparent ☐
- d) It is allowed only subject to the approval of a committee in the case of

i) all donors

☐

OR

- ii) certain categories of donor (please specify which groups) ☐

- e) Other conditions or criteria (please specify)

.....  
Whether you have legislation or not are there guidelines, working parties, codes or other materials specifying clinical conditions/criteria (if yes please give details)?

**3. Consent**

The issue of consent to medical treatment is usually regarded as an important part of the process of LDT. In particular the EUROTOLD group wishes to understand the legal and ethical dimensions of disclosure of information and voluntariness in donation. Any information you have relating to general consent provisions and/or legislation dealing specifically with consent in LDT would be valuable to us.

- (i) If you have legislation relating to LDT does it provide general criteria relating to the issue of consent in terms of:-

- a) the form by which consent is to be obtained

Yes ☐

Please give details?



**3 A (v) LEGAL CODING SYSTEM**  
**TRANSPLANT LEGISLATION**  
(coding for analysis of Centre and Attitudes Questionnaire Results)

Scale = very permissive toward LDT to very restrictive.

Clinical Conditions

Law requires LDT used if no other viable option	- 5
Law requires LDT to be likely to produce a better result/than cadaveric transplantation	- 3
Law requires histocompatibility between donor and /recipient	- 1
Law requires a high level of histocompatibility	- 4
Law requires authorisation by an independent committee	- 2
Law requires authorisation by independent physicians	- 1

Class of Donor

Law excludes donation by non-closely genetically related	- 4
Law restricts very strongly	- 3
Law restricts to a degree	- 2
No provisions re: unrelated donors	0
Law facilitates but no restrictions	+ 2

Minors as Donors

Law allows all minors to donate kidneys	+ 2
Law allows minors with capacity to donate	+ 1
Law permits donation subject to some restrictions	0
Law permits donation subject to strong restrictions	- 1
Law prohibits minors from donating	- 2

**3A(vi): ATTITUDE QUESTIONNAIRE - CODING (GENERAL)**

- |    |                               |  |
|----|-------------------------------|--|
| 1. | <u>General</u>                | Most positive score = most positive attitude towards LDT.  |
| 2. | <u>Related/Unrelated</u>      | The more liberal towards unrelated donors, the higher the score (Q. nos. 1, 2, 6, 11 & 12) ie. the most liberal regarding LDT generally.     |
| 3. | <u>Dialysis/Pre-dialysis</u>  | Higher the score the more liberal towards LDT in terms of favourability toward transplant pre-dialysis (Q. nos. 5 & 8). (Q. 8 is ambiguous). |
| 4. | <u>Age</u>                    | Higher the score the less age is a factor ie. broader age range acceptable. (Q. nos. 1(?), 4(?), 6, 7, 10, 11 & 12).                         |
| 5. | <u>Type of Relationship</u>   | Difficult to code : either it overlaps with (2) above or cannot be properly coded.   |
| 6. | <u>Dialysis vs Transplant</u> | Plus and minus. The higher the plus score, the more favourable towards transplantation. (Q. nos. 1, 2, 4, 5, 6, 7, 9, 10, 11 & 12).          |

**CODING**

Q. nos. 1       -----



	2	<u>Related/Unrelated</u>				
Q. nos. 1	(a) =	+3	(b) =	-1		
	2	(a) =	+2	(b) =	-1	(c) = 0
	6	(a) =	+3	(b) =	0	(c) = -1
Ranking of(	11	(a) =	+3	(b) =	+2	(c) = +2
husband (	12	(a) =	+2	(b) =	+1	(c) = +1
						(d) = -1*
						(d) = -1*

	3	<u>Dialysis/Pre-dialysis</u>			
Q. nos. 5	(a) =	+3	(b) =	0	(c) = -2
	4	(a) =	+2	(b) =	-2

	4	<u>Age</u>			
Q. nos. 6	(a) =	+3	(b) =	-1	(c) = -1
	7	(a) =	+3	(b) =	-2
	10	(a) =	0	(b) =	+1
Ranking of	11	(a) =	0	(b) =	0
daughter					(c) = 0
					(d) = 0
Ranking of son	12	(a) =	+3	(b) =	+1
					(c) = +1
					(d) = -2

\* This is an assessment based on first choice only  
\*\* Assumes no answer if not prepared to use either

6      Dialysis vs Transplantation

Q. nos. 1	(a) =	+2	(b) =	0		
	2	(a) =	+2	(b) =	+2	(c) = -2
	4	(a) =	+1	(b) =	-1	(re: (b), obviously the
						greater number of years, the higher the minus score).
	5	(a) =	+2	(b) =	+1	(c) = -2
	6	(a) =	+2	(b) =	+2	(c) = -2
	7	(a) =	+2	(b) =	-3	(c) = -2
	9	(a) =	+2	(b) =	-1	
	10	(a) =	+2	(b) =	+2	(c) = -2
	11	(a) =	+1	(b) =	+1	(c) = +1
						(d) = -2*
	12	(a) =	+1	(b) =	+1	(c) = +1
						(d) = -2*

\* Based on first choice only

3B: Results.

TRANSPLANT CENTRES QUESTIONNAIRE

Cadaver tx summary - all centres								
n	av-pop(m)	av-wait	start-cad	av-tot-cad	av-cadrate	liv-legal		not
AR 1	3.0	5.0	1991	22.0	1.7	1	0	
AU 4	1.6	191.2	1970	837.0	44.0	3	1	
BE 5	1.2	143.4	1963	909.8	34.7	2	3	
CY 1	0.5	70.0	1987	122.0	34.0	1	0	
CZ 2	1.1	106.5	1961	357.5	24.9	2	0	
DE 4	1.0	73.2	1967	946.0	50.9	4	0	
ES 1	1.5	65.0	1968	197.0	6.0	1	0	
FR 12	1.7	158.8	1963	939.5	68.6	10	2	
GE 14	2.3	282.6	1967	863.3	23.6	13	1	
GR 1	3.0	954.0	1983	265.0	7.2	1	0	
HO 4	1.8	187.5	1967	856.5	36.9	4	0	



HU	4	2.4	306.0	1973	476.5	23.5	1	3
IT	8	2.5	306.6	1966	395.9	13.8	5	3
NO	1	4.2	135.0	1969	1955.0	29.0	1	0
PO	4	3.2	1530.0	1965	728.0	23.1	3	0
RO	1	10.0	30.0	-1	NA	NA	1	0
SK	2	1.6	180.0	1991	115.0	10.0	2	0
SP	10	2.0	113.4	1965	427.8	38.4	5	5
SW	3	1.7	82.7	1964	1142.0	30.7	3	0
UK	20	2.0	146.0	1963	917.3	29.0	20	0

Forsee expansion of ld prog.?

	Yes	No	Maybe
AR	1	0	0
AU	2	0	2
BE	1	3	1
CY	1	0	0
CZ	1	0	1
DE	3	1	0
ES	1	0	0
FR	7	2	3
GE	7	3	4
GR	0	0	1
HO	3	1	0
HU	0	0	1
IT	6	1	1
NO	0	1	0
PO	3	1	0
RO	1	0	0
SK	1	0	1
SP	3	2	4
SW	2	0	1
UK	11	1	8

% consider cadaver BEFORE dial needed = 40  
% WHEN = 51  
% AFTER period of dial = 9  
% And by country:

	Before dial. needed	When dial. needed	After period dial.
AR	1	0	0
AU	1	3	0
BE	3	2	0
CY	0	1	0
CZ	0	2	0
DE	3	1	0
ES	0	1	0
FR	9	3	0
GE	2	10	2
GR	0	0	1
HO	2	1	0
HU	3	1	0
IT	1	4	3
NO	1	0	0
PO	0	4	0
RO	0	0	1
SK	0	1	1
SP	4	6	0
SW	1	2	0
UK	9	9	1

Correlations with legal scores:

	Consider legal	Forsee expansion
1. Clin conds	0.3042	0.24763
2. Restr. on non-close rel.	-0.0513	0.00704
3. Restr. on risks	0.2242	0.29439
4. 1-3 combined	0.3468	0.35363
5. Minors	0.0389	0.00563
6. Status of law	-0.2694	-0.43385
7. Financial comp.	-0.4859	-0.30734
8. Time law in place	-0.2216	-0.16173
9. Overall	-0.3057	-0.37462

Living donor centres only

	n	start-liv	av-tot-liv	av-livrate	Min age	Max age
AU	3	1973	58.0	4.7	15	75
BE	4	1963	143.3	4.0	18	70
CY	1	1986	135.0	22.0	21	75
CZ	1	1990	5.0	NA	20	60
DE	4	1968	103.2	11.2	1	75
ES	1	1972	43.0	4.3	18	70
FR	10	1052	75.1	5.8	18	70
GE	12	1970	27.9	1.9	6	75
GR	1	1983	326.0	11.0	25	75
HO	4	1968	101.0	5.1	10	80
HU	2	1974	42.0	0.6	18	60
IT	8	1967	101.9	3.6	16	5
NO	1	1969	1241.0	18.6	18	NA
PO	3	1966	26.3	0.8	16	75
RO	1	1980	34.0	NA	30	70
SK	2	1994	3.0	NA	18	60
SP	6	1965	77.3	3.7	18	75
SW	3	1964	289.7	12.8	18	75
UK	20	1961	86.7	2.2	16	80



When consider for living donor transplant?					
	n	Pre-dial.	At dial	At cad list	After cad list
AU	3	2	1	0	0
BE	4	2	1	0	0
CY	1	0	1	0	0
CZ	1	1	0	0	0
DE	4	4	0	0	0
ES	1	0	1	0	0
FR	10	8	0	0	1
GE	12	3	4	4	1
GR	1	0	0	0	1
HO	4	3	0	1	0
HU	2	1	1	0	0
IT	8	4	4	0	0
NO	1	1	0	0	0
PO	3	0	3	0	0
RO	1	0	0	0	1
SK	2	0	0	1	1
SP	6	3	1	0	2
SW	3	1	2	0	0
UK	20	12	3	2	1

Exclusion criteria:

- 1= Antihypertens. drugs
- 2=Family hypertens.
- 3=Diet controlled diabetes
- 4=Ins. dep. diabetes
- 5=Kidney stones
- 6=Unexplained micros. haematuria
- 7= Proteinuria
- 8=Deep vein thromb.

	n	1	2	3	4	5	6	7	8
AU	3	3	0	2	3	3	3	3	3
BE	4	3	1	3	4	4	4	4	2
CY	1	0	0	0	1	1	0	1	1
CZ	1	1	0	1	1	1	1	1	0
DE	4	3	0	2	4	3	4	4	2
ES	1	1	0	1	1	1	1	1	1
FR	10	10	0	8	10	8	6	9	7
GE	12	9	0	7	12	9	11	11	8
GR	1	0	0	1	1	1	1	1	0
HO	4	2	0	3	4	1	4	4	1
HU	8	7	0	6	7	6	8	8	4
NO	1	1	0	1	1	1	1	1	1
PO	3	3	0	2	3	3	3	3	1
RO	1	1	0	0	1	1	1	1	1
SK	2	2	0	0	2	2	2	1	2
SP	6	3	0	5	6	5	4	6	6
SW	3	2	0	2	3	2	1	2	1
UK	20	13	0	13	18	17	14	16	11

Correlation with legal scores:

	Consider spouse		Min age
1. Clin conds	-0.071	0.099	
2. Restr. on non-close rel.	0.280	0.059	
3. Restr. on risks	-0.174	0.388	
4. 1-3 combined	0.011	0.304	
5. Minors	0.235	-0.431	
6. Status of law	0.129	0.064	

What relatives will they consider?

	n	Prnt	Sblg	Sp's	Rl(mr.)	G/pnt	Sn/dgh	Frnd	Oth
AU	3	3	3	1	0	2	1	0	0
BE	4	4	4	2	1	3	3	1	0
CY	1	1	1	1	1	1	1	1	0
CZ	1	1	1	0	0	0	0	0	0
DE	4	4	4	4	2	3	1	0	1
ES	1	1	1	1	1	0	0	1	0
FR	10	9	9	0	0	2	4	0	0
GE	12	12	12	4	1	4	6	0	0
GR	1	1	1	1	0	1	0	0	0
HO	4	4	4	2	1	2	3	1	0
HU	2	2	2	0	0	0	2	0	0
IT	8	8	8	7	3	4	4	0	0
NO	1	1	1	1	1	1	1	0	0
PO	3	3	3	3	0	2	1	0	0
RO	1	1	1	0	0	1	0	0	0
SK	2	2	2	2	2	2	2	0	0
SP	6	6	6	2	0	3	3	0	0
SW	3	3	3	3	1	3	2	0	1
UK	20	20	20	16	6	13	10	5	1

Mean values for other variables:

1=Min age							
2=Max age							
3=Max syst bp							
4=Max diast bp							
5=Max obesity							
6=Waiting time (months)							
	n	1	2	3	4	5	6
AU	3	18	58	148	95	28	3
BE	4	18	65	140	90	28	4
CY	1	21	75	160	90	NA	NA
CZ	1	20	60	160	100	NA	NA
DE	4	12	73	150	105	20	3
ES	1	18	70	150	95	20	2
FR	10	18	61	142	86	20	3
GE	12	17	68	150	90	28	3
GR	1	25	75	140	90	20	6
HO	4	17	75	156	91	28	4
HU	2	18	55	145	90	20	3
IT	8	18	65	154	93	27	4
NO	1	18	NA	140	90	35	5
PO	3	17	67	153	100	37	2
RO	1	30	70	150	90	NA	NA
SK	2	18	60	161	91	25	2
SP	6	19	65	152	93	31	3
SW	3	21	75	145	93	20	8
UK	20	19	68	151	89	29	5

Strict clin. excl. crit.

- 0.168
- 0.025
- 0.234
- 0.247
- 0.165
- 0.120



7. Financial comp.	-0.243	-0.111	0.067
8. Time law in place	-0.036	0.144	-0.386
9. Overall	0.127	-0.123	-0.280

**LD PROGRAMMES ONLY:**

% Written guidelines: 36.05  
% Written protocol : 66.67

% Consider liv. don. BEFORE dial needed = 60  
% WHEN = 29.33  
% AFTER period of dial = 10.67

Would consider as potential donor (%)  
Parent 98.84999999999999 Sibling 98.84999999999999  
Spouse 57.47 Rel by marr. 22.99  
G/parent 54.02 Son/daught 52.87  
Friend 10.34 Other 3.45

Used in approaching prospective donors (%)  
Patient 71.76000000000001 Spouse/parent 38.82  
Tx coord. 11.76 Neph. staff 45.88

% Discuss financial implications: 43.53 % Financial help available: 36.05

% Require min HLA match: 53.49

Min age: 1 30 Max age: 40 80  
% Attempt age match: 19.77

Exclusions (%)  
Antihypertensive drugs for bp 76.73999999999999 Family history hypertension 1.15  
Diet controlled diabetes 67.44 Ins. dependent diabetes 96.55  
Kidney stones 82.56 Unexplained micro. haematuria 81.40000  
Proteinuria 90.7 Dp vein thrombophelb/embol 64.2900000  
Max obesity levels (%): 10 50

% Donor psych. evaluation: 32.18  
% HIV test donors: 96.510  
Mean wait to ld tx (months): 3.8

**ATTITUDES SUMMARY**

Number of questionnaires= 311

Responses (%) (Note that for some questions it is reasonable to answer yes to more than one response, so percentages need not sum to 100).

Q1 55-year-old with friend...  
(a) Type and investigate 40.84  
(b) Refuse to consider 58.2

Q2 50-year-old wants India...  
(a) Let go 24.12  
(b) Offer cadaver tx 23.79  
(c) Leave on list 54.66

Q3 Ideal donor for 36-year-old...  
(a) Cadaver 43.41  
(b) Liv rel. 56.59

Q4 45-year-old with brother...  
(a) Accept brother 77.48999999999999  
(b) Wait for cadaver 21.54  
If (b), mean wait (yrs) before use brother = 3.09  
with distn:  
1 2 3 4 5 6  
10 24 10 3 10 9  
where code 6 implies 6 or more years.



Q5 20-year-old with 4 match mother...

- (a) Tx mother pre dial. 57.23
- (b) Put on list for 6 months 26.05
- (c) Put on list for 2 years 15.43

Q7 14-year-old with twin...

- (a) Accept twin 36.01
- (b) Wait for good cadaver match 39.23
- (c) Wait for bld gp comp. cadaver 25.4

Q9 20-year-old with diabetic mother...

- (a) Accept mother 19.29
- (b) Leave on list 79.73999999999999

Q11 45-year-old female... Choose from

- 1. 4 antigen match daughter
- 2. Bld gp comp husband
- 3. 4 antigen match sister
- 4. Leave on list

Option 1 selected first/second/third/not at all (%):  
26.09 11.04 6.69 56.18

Option 2 selected first/second/third/not at all (%):  
17.06 8.699999999999999 11.71 62.53

Option 3 selected first/second/third/not at all (%):  
29.77 10.03 5.35 54.85

Option 4 selected first/second/third/not at all (%):  
27.09 43.14 6.35 23.42

Q6 70-year-old with husband/daughter...

- (a) Accept spouse 13.83
- (b) Accept daughter after antihypn tmt. 11.58
- (c) Leave on list 72.98999999999999

Q8 40-year-old with 2 brothers...

- (a) Accept 38-year-old, unmarried... 74.28
- (b) Accept 56-year-old, married... 20.58

Q10 37-year-old with brother/father...

- (a) Accept brother 24.12
- (b) Accept father 50.8
- (c) Wait for good cadaver match 27.33

Q12 36-year-old female... Choose from

- 1. Bld gp comp husband
- 2. 4 antigen match son aged 18
- 3. 6 antigen match sister
- 4. Leave on list

Option 1 selected first/second/third/not at all (%):  
26.33 8.33 7.67 57.67

Option 2 selected first/second/third/not at all (%):  
12.67 12.33 6.33 68.67

Option 3 selected first/second/third/not at all (%):  
33.67 5.67 6 54.66

Option 4 selected first/second/third/not at all (%):  
27.33 46.33 6.33 20.01

Largest inter-question correlations:

- 4a 5a 0.483                      4a 5c -0.537
- 4b 5a -0.48                      4b 5c 0.512

Related/unrelated score analysis:  
Higher scores indicate more positive attitude to unrelated tx.

Overall related/unrelated score summary

	n	mean	sd
AL	1 2.0	0.0	
AR	2 8.0	4.2	
AU	4 1.0	2.4	
BE	16	-0.2	4.4
CY	1	-3.0	0.0
CZ	4	-2.8	2.1
DE	7 4.1	2.1	
ES	1	-2.0	0.0
FR	24 -1.0	3.6	
GE	25 0.2	4.5	
GR	2 0.0	2.8	
HO	4 1.2	5.9	
HU	27 0.2	2.7	
IT	10 3.7	3.3	
NO	1 7.0	0.0	
PO	104	4.0	4.6
RO	1	-4.0	0.0
SK	3 7.0	3.6	
SL	6	-1.7	1.0
SP	20 1.0	3.2	



SW 6 3.8 2.0  
UK 42 2.1 4.1

Rel/unrel score by speciality (n,mn,sd):

Surgeon 100 2.2 4.5  
Nephrologist 161 1.7 4.3  
Other 50 2.8 5

Correlations with centre statistics:

Wait list/m Cad rate/m Tot cad LD rate/m Tot LD  
-0.047 -0.083 0.191 0.175 0.249

Mean,sd score for 164 people at centres with LD program= 1.47 4.09  
Mean,sd score for 34 people at centres without LD program= -1.09 3.1  
T-test= 3.444 p= 0.00059999999999999999

Dialysis/pre-dialysis score analysis:

Higher scores indicate more liberal attitude to pre-dial tx.

Overall dial/pre-dial score summary

	n	mean	sd
AL	1 5.0	0.0	
AR	2 2.0	0.0	
AU	4 1.8	4.3	
BE	16 0.6	4.5	
CY	1 5.0	0.0	
CZ	4 3.5	1.7	
DE	7 4.4	1.5	
ES	1 2.0	0.0	
FR	24 3.1	3.0	
GE	25 1.7	3.7	
GR	2 2.0	0.0	
HO	4 5.0	0.0	
HU	27 1.1	3.3	
IT	10 5.0	0.0	
NO	1 5.0	0.0	
PO	104	2.8	2.8
RO	1 2.0	0.0	
SK	3 1.0	4.6	
SL	6 1.8	3.3	
SP	20 0.8	3.8	
SW	6 5.0	0.0	
UK	42 3.1	2.9	

Dial/pre-dial score by speciality (n,mn,sd):

Surgeon 100 3.1 2.8  
Nephrologist 161 2.1 3.3  
Other 50 2.6 3.4

Correlations with centre statistics:

Wait list/m Cad rate/m Tot cad LD rate/m Tot LD  
0.043 0.007 0.213 0.232 0.215

Mean,sd score for 164 people at centres with LD program= 2.93 3.16  
Mean,sd score for 34 people at centres without LD program= -0.26 3.14  
T-test= 5.379 p= 0

Age-attitude score analysis:

Higher scores indicate age less of a factor

Overall age-attitude score summary

n	mean	sd
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AL 1	2.0	0.0
AR 2	2.0	1.4
AU 4	-0.2	2.6
BE 16	0.6	5.2
CY 1	3.0	0.0
CZ 4	-0.8	4.3
DE 7	-0.9	1.5
ES 1	-2.0	0.0
FR 24	0.3	3.6
GE 25	0.2	4.7
GR 2	-2.0	2.8
HO 4	0.2	3.9
HU 27	-1.1	3.3
IT 10	4.0	2.9
NO 1	7.0	0.0
PO 104	3.2	3.4
RO 1	1.0	0.0
SK 3	-1.0	2.0
SL 6	-1.3	1.6
SP 20	-1.6	3.9
SW 6	-1.2	1.6
UK 42	1.2	4.4

#### Age-attitude score by speciality

	(n,	mn,	sd):
Surgeon	100	1.3	4.4
Nephrologist	161	1.1	4
Other	50	1.1	3.6

#### Correlations with centre statistics:

Wait list/m Cad rate/m Tot cad LD rate/m Tot LD  
 -0.024 -0.059 0.302 0.037 0.165

Mean,sd score for 164 people at centres with LD program= 0.7199999999999999 4

Mean,sd score for 34 people at centres without LD program= -2.56 3.17

T-test= 4.488 p= 0

#### Dialysis/transplantation score analysis:

Higher scores indicate more positive attitude to tx.

#### Overall dial/tx score summary

	n	mean	sd
AL 1	1.0	0.0	
AR 2	5.0	0.0	
AU 4	-1.8	5.6	
BE 16	-5.4	9.2	
CY 1	11.0	0.0	
CZ 4	2.8	5.9	
DE 7	2.7	1.4	
ES 1	-1.0	0.0	
FR 24	-2.2	6.7	
GE 25	-3.0	10.1	
GR 2	-2.0	2.8	
HO 4	1.5	3.0	
HU 27	-3.3	6.4	
IT 10	7.4	2.8	
NO 1	10.0	0.0	
PO 104	5.3	5.9	
RO 1	-3.0	0.0	
SK 3	5.7	4.5	
SL 6	-2.3	4.1	
SP 20	-4.2	8.1	



SW 6 1.7 2.6  
UK 42 0.9 8.3

Dial/tx score by speciality (n,mn,sd):

Surgeon	100	1.8	8
Nephrologist	161	0.7	7.5
Other	50	1.1	8.6

Correlations with centre statistics:

Wait list/m	Cad rate/m	Tot cad	LD rate/m	Tot LD
-0.014	-0.055	0.165	0.215	0.234

Mean,sd score for 164 people at centres with LD program= 0.34 7.43  
Mean,sd score for 34 people at centres without LD program= -7.68 7.43  
T-test= 5.726 p= 0

Correlations with legal scores:

	Rel/unrel	Dial/pre dial	Age	Dial/tx
1. Clin conds	-0.1226	0.4266	0.08664	0.14992
2. Restr. on non-close rel.	0.1245	-0.0394	-0.00372	0.15832
3. Restr. on risks	-0.3525	-0.1307	-0.31818	0.25756
4. 1-3 combined	-0.2018	0.2921	-0.07254	0.09912
5. Minors	0.1784	0.4314	0.18623	0.34493
6. Status of law	0.0495	0.0867	0.10633	0.19678
7. Financial comp.	-0.0655	-0.4510	-0.17508	0.41689
8. Time law in place	-0.2167	0.0613	-0.23959	0.00646
9. Overall	0.0233	0.2213	0.08234	0.20840

Question 13 Summary

The tables below show, by potential donor, the percentage of respondents selecting codes 1-5 for each recipient:

- Recipient A = 5-year-old boy
- Recipient B = 18-year-old girl
- Recipient C = 40-year-old woman
- Recipient D = 70-year-old man

Codes: 1 = Tx contraindicated  
2 = Tx possible with appropriate treatment  
3 = Tx suitability requires discussion  
4 = Tx is appropriate  
5 = Unsure

Total number of respondents is 184

1 Blood Pressure 148/90 46 M

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	41	27	21	47
Choice 2:	16	26	32	14
Choice 3:	21	21	16	23
Choice 4:	14	24	30	14
Choice 5:	8	2	2	3

2 Breast Cancer 20 years ago 53 F

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	68	59	50	58
Choice 2:	1	1	2	2
Choice 3:	17	22	23	26
Choice 4:	7	13	20	11



Choice 5:        7        6        5        3

3 Trace of proteinuria        57 F

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	60	47	39	53
Choice 2:	5	8	11	5
Choice 3:	24	35	37	31
Choice 4:	4	8	10	7
Choice 5:	5	3	4	4

4 Two previous urinary infections    26 F

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	19	11	14	46
Choice 2:	24	33	31	18
Choice 3:	25	21	22	20
Choice 4:	26	32	30	12
Choice 5:	6	3	3	3

5 Maturity onset diabetes        68 M

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	89	82	70	62
Choice 2:	2	4	11	11
Choice 3:	5	9	11	18
Choice 4:	1	3	4	7
Choice 5:	3	2	3	2

6 Previous history hepatitis A    33 M

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	17	13	14	44
Choice 2:	6	7	7	4
Choice 3:	16	15	16	22
Choice 4:	53	62	60	28
Choice 5:	8	3	3	3

7 HIV -ve, Haemophiliac        25 F

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	90	90	90	92
Choice 2:	2	2	2	1
Choice 3:	4	5	6	5
Choice 4:	2	2	2	2
Choice 5:	1	0	0	0

8 4 dependent children        42 M

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	34	29	30	62
Choice 2:	1	1	1	1
Choice 3:	33	38	40	22
Choice 4:	26	28	25	11
Choice 5:	7	5	4	4

9 Treated depression        76 M

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	78	74	63	64
Choice 2:	3	3	8	7
Choice 3:	11	14	17	17
Choice 4:	7	7	11	11



Choice 5:        2        1        1        1

10 Unemployed                      31 M

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	12	8	8	37
Choice 2:	2	2	2	1
Choice 3:	14	12	18	29
Choice 4:	66	76	70	31
Choice 5:	6	2	2	3

11 Serving army officer              30 M

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	15	11	13	43
Choice 2:	2	2	2	1
Choice 3:	14	13	18	26
Choice 4:	65	72	65	26
Choice 5:	5	2	2	5

12 IV drug user                      23 F

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	92	93	91	92
Choice 2:	2	2	2	1
Choice 3:	3	4	7	6
Choice 4:	1	0	0	1
Choice 5:	2	1	1	1

13 Myocardial infarct. 5 years ago 54 F

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	72	64	58	71
Choice 2:	5	6	7	3
Choice 3:	17	22	24	16
Choice 4:	2	4	7	6
Choice 5:	4	4	4	4

14 Previous deep vein thrombosis 68 M

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	70	56	46	54
Choice 2:	9	14	17	11
Choice 3:	16	22	28	25
Choice 4:	1	5	7	8
Choice 5:	4	3	2	2

15 Bilateral calf claudication 70 F

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	89	86	80	80
Choice 2:	2	1	3	3
Choice 3:	4	7	10	12
Choice 4:	1	1	2	1
Choice 5:	5	5	5	4

16 Smokes 40 per day              52 F

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	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	54	42	35	53
Choice 2:	8	8	11	9
Choice 3:	23	31	36	25
Choice 4:	12	17	17	10



Choice 5:           3           1           1           3

17 Enuresis                           14 M

	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	72	70	76	84
Choice 2:	5	5	3	3
Choice 3:	7	9	8	6
Choice 4:	10	12	10	7
Choice 5:	5	4	2	1

18 Self employed builder           18 F

	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	17	16	31	59
Choice 2:	2	2	2	1
Choice 3:	26	24	26	16
Choice 4:	48	54	36	20
Choice 5:	6	4	5	4

19 Epilepsy                           16 M

	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	61	62	67	81
Choice 2:	9	7	5	3
Choice 3:	11	10	12	8
Choice 4:	15	17	12	7
Choice 5:	4	4	3	2

20 Winter bronchitis               78 M

	Recipient A	Recipient B	Recipient C	Recipient D
Choice 1:	81	77	71	68
Choice 2:	3	5	8	9
Choice 3:	5	7	10	8
Choice 4:	7	8	9	12
Choice 5:	4	4	2	3

ADDITIONAL RESULTS

Estimated living-cadaver tx ratio (1993/1994)  
(Centres with complete info. only)

n	Mean ratio (%)	Min	Median	Max
BE 4	3.2	0.0	2.3	8.2
CY 1	64.7	64.7	64.7	64.7
CZ 1	0.0	0.0	0.0	0.0
DE 4	24.3	14.1	21.3	40.4
ES 1	72.2	72.2	72.2	72.2
FR 9	7.7	0.0	4.0	23.9
GE 11	8.1	0.0	5.7	24.6
GR 1	153.5	153.5	153.5	153.5
HO 4	15.0	7.1	11.8	29.2
HU 2	1.2	0.0	1.2	2.3
IT 8	27.6	0.0	22.4	104.0
NO 1	63.9	63.9	63.9	63.9
PO 3	2.1	0.0	1.4	4.8
SK 1	0.0	0.0	0.0	0.0
SP 6	7.6	1.2	3.7	29.0
SW 3	41.9	33.7	36.4	55.8
UK 19	7.2	0.0	5.4	31.8

Forsee expansion of ld prog.?

n	Yes	No	Maybe	Yes(%)	No(%)	Maybe(%)
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**PAGE**

**NUMBERING**

**AS ORIGINAL**



SW : 25 19 18  
UK : 18 18 20 18 18 18 18 16 16 18 21 18 25 20 21 21 16

5 1

what relationships considered in LDT as percentages

	n	Prnt(%)	Sib(%)	Spse(%)	Rel(m)(%)	G/prnt(%)	S/d(%)	Frnd(%)	Other(%)
AU	3	100	100	33.3	0.0	66.7	33.3	0	0.0
BE	4	100	100	50.0	25.0	75.0	75.0	25	0.0
CY	1	100	100	100.0	100.0	100.0	100.0	100	0.0
CZ	1	100	100	0.0	0.0	0.0	0.0	0	0.0
DE	4	100	100	100.0	50.0	75.0	25.0	0	25.0
ES	1	100	100	100.0	100.0	0.0	0.0	100	0.0
FR	10	90	90	0.0	0.0	20.0	40.0	0	0.0
GE	12	100	100	33.3	8.3	33.3	50.0	0	0.0
GR	1	100	100	100.0	0.0	100.0	0.0	0	0.0
HO	4	100	100	50.0	25.0	50.0	75.0	25	0.0
HU	2	100	100	0.0	0.0	0.0	100.0	0	0.0
IT	8	100	100	87.5	37.5	50.0	50.0	0	0.0
NO	1	100	100	100.0	100.0	100.0	100.0	0	0.0
PO	3	100	100	100.0	0.0	66.7	100.0	0	0.0
RO	1	100	100	0.0	0.0	100.0	0.0	0	0.0
SK	2	100	100	100.0	100.0	100.0	100.0	0	0.0
SP	6	100	100	33.3	0.0	50.0	50.0	0	0.0
SW	3	100	100	100.0	33.3	100.0	66.7	0	33.3
UK	20	100	100	80.0	30.0	65.0	50.0	25	5.0

By speciality:  
Overall numbers:  
39 Surgery, 49 Nephrology, 2 Anaesthesia and 7 Other  
With LD progs:  
36 Surgery, 39 Nephrology, 2 Anaesthesia and 6 Other  
Percentages:  
Forsee expansion?  
Surgery Nephrology Anaesthesia Other  
Yes 56.76 45.83 100 83.33  
No 10.81 22.92 0 0.00  
Maybe 32.43 31.25 0 16.67

Law prevents?  
Surgery Nephrology Anaesthesia Other  
Yes 12.82 20.41 0 42.86  
No 87.18 79.59 100 57.14

When consider cadaver donor tx?  
Surgery Nephrology Anaesthesia Other  
Before dial 46.15 41.67 0 33.33  
When dial 38.46 52.08 100 66.67  
After dial 15.38 6.25 0 0.00

When consider living donor tx?  
Surgery Nephrology Anaesthesia Other  
Before dial 62.86 56.76 0 33.33  
When dial 25.71 18.92 100 16.67  
At list 5.71 8.11 0 50.00  
After list 5.71 16.22 0 0.00

Who consider?

	Surgery	Nephrology	Anaesthesia	Other
Parent	100.00	97.44	100	100.00
Sibling	100.00	100.00	100	83.33
Spouse	69.44	46.15	0	50.00



Rel by marr.	30.56	15.38	0	33.33
G/parent	66.67	53.85	0	0.00
Son/daught	52.78	48.72	0	83.33
Friend	16.67	5.13	0	0.00
Other	2.78	5.13	0	0.00



## Appendix 4: Background Materials on Carl Rogers and the Person Centred Approach.

### 4A: Introduction.

The person centred approach has been referred to on a number of occasions throughout the PhD including chapters 4, 5 and 8. The approach was a key part of the process of interviewing of living donors and recipients. This appendix provides a brief outline of the person centred approach.

### 4B: The Person Centred Approach.

Rogers initially described his approach as client-centred in recognition of the fact that his work in psychotherapy and counselling was focused around the needs of the client who was regarded as sovereign over her own process by the therapist as distinct from the therapist taking an authoritarian stance. Later however in recognition that the same way of working was applied to a variety of aspects of human interaction (such as teaching, therapeutic groups, business, partners/couples etc.) the approach was renamed person-centred.

Rogers felt that given the inherent capacity of the organism to grow if he provided the appropriate conditions he would act as an agent of change for those he was working with such that they might come to progressively let go of that which was standing in between them and further evolution.

"If I can provide a certain type of relationship the other person will discover within himself the capacity to use the relationship for growth and change and personal development will occur."<sup>1</sup>

Rogers initially tended to describe this type of relationship in general terms of having integrity and respect for the inherent value of persons. While this remained part of his perspective he later began to describe a facilitative relationship as necessarily characterized by three attitudes which integrated together formed a constructive way of being with other persons. These conditions were congruence (being real/authentic/genuine), empathy (attunement with the process of the other person) and unconditional positive regard (a warmth and prizing of the value of the other person). The following is a detailed verbatim extract in which Rogers discusses the three core attitudes in detail.<sup>2</sup>

"The order in which these therapeutic conditions are described has some significance because they are logically intertwined. In the first place, the therapist must achieve a strong, accurate empathy. But such deep sensitivity to the moment-to-moment "being" of another person requires that the therapist first accept, and to some degree prize, the other person. That is to say, a sufficiently strong empathy can scarcely exist without a considerable degree of unconditional positive regard. However, since neither of these conditions can possibly be meaningful in the relationship unless they are real, the therapist must be, both in these respects and in others, integrated and genuine within the therapeutic encounter. Therefore, it seems to me that genuineness or congruence is the most basic of the three conditions. I shall try to describe its meaning.

We readily sense this quality of congruence in everyday life. We all know persons who always seem to operate from behind a front, who play a role, who tend to say things they do not feel. They are exhibiting incongruence. We tend not to reveal ourselves too deeply to such people. On the other hand, we all know individuals whom we trust because we sense that they actually are as they present themselves to be, openly and transparently - that we are dealing with the person himself, not a polite or professional facade. This is genuineness.

Genuineness in therapy means that the therapist is his actual self during his encounter with his client. Without facade, he openly has the feelings and attitudes that are flowing in him at the moment. This involves self-awareness; that is, the therapist's feelings are available to him - to his awareness - and he is able to live them, to experience them in the relationship, and to communicate them if they persist. The therapist encounters his client directly, meeting him person to person. He is *being* himself, not denying himself.

Since this concept is liable to misunderstanding, let me state that it does not mean that the therapist burdens his client with overt expression of all his feelings. Nor does it mean that the therapist discloses his total self to his

<sup>1</sup> Rogers, 'On Becoming a Person; A Therapist's view of Psychotherapy,' Constable, 1961 at p33.

<sup>2</sup> H.Kirschenbaum and V.L.Henderson (ed), Carl Rogers Dialogues, Constable, 1989, 11 - 16.



client. It does mean, however, that the therapist denies to himself none of the feelings he is experiencing and that he is willing to experience transparently any *persistent* feelings that exist in the relationship and to let these be known to his client. It means avoiding the temptation to present a facade or hide behind a mask of professionalism, or to assume a confessional-professional attitude.

It is not simple to achieve such a reality. Being involves the difficult task of being acquainted with the flow of experiencing going on within oneself, a flow marked especially by complexity and continuous change. So, if I sense that I am feeling bored by a client and if this feeling persists, I think I owe it to him and our relationship to share my feeling with him. The same will hold if my feeling were fear, or if my attention were so focused on my own problems that I could scarcely listen to him. But, as I attempt to share such feelings with him, I want also to be constantly in touch with what is going on in me. If I am, I will recognize that I am expressing my own feeling of being bored and not some supposed fact about him as a boring person. When voiced as my own reaction, such an expression can lead to a deep relationship. But my feeling exists in the context of a complex and changing flow, which also needs to be communicated. I would like to share with him my distress at feeling bored and my discomfort in expressing it. As I do, I find that my boredom arises from my sense of remoteness from him and that I would like to be in closer touch with him; and even as I try to express these feelings they change. I am certainly not bored as I wait with eagerness, and perhaps a bit of apprehension, for his response. I also feel a new sensitivity to him now that I have shared this feeling which has been a barrier between us. I am far more able to hear the surprise, or perhaps the hurt, in his voice as he now finds himself speaking more genuinely because I have dared to be real with him. I have let myself be a person - real, imperfect - in my relationship with him.

It should be clear from this lengthy description that the concept of congruence implies that it is helpful to be genuine even when negative feelings toward the client are involved. It would probably be most helpful if these feelings did not exist in the therapist. However, our theory implies that it would be more harmful if these negative feelings were hidden. Even with such negative attitudes, which seem so potentially damaging but which all therapists have from time to time, I am suggesting that it is preferable for the therapist to be real than to put on a false posture of interest, concern, and liking that the client is likely to sense as false.

It is not easy for a client, or for any human being, to entrust his most deeply shrouded feelings to another person. It is even more difficult for a disturbed person to share his deepest and most troubling feelings with a therapist. The genuineness of the therapist is one of the elements in the relationship that make the risk of sharing easier and less fraught with dangers.

#### *Unconditional Positive Regard.*

The second condition that seems to me essential for therapeutic movement and change is an unconditional positive regard for the client. This means that the therapist communicates to his client a deep and genuine caring for him as a person with human potentialities, a caring uncontaminated by evaluations of the patient's thoughts, feelings, or behavior. The therapist experiences a warm acceptance of his client's experience as a part of that person and places no conditions on his acceptance and warmth. He prizes the client in a total, rather than a conditional, way. He does not accept certain feelings in the client and disapprove of others. He feels an unconditional positive regard for this person. This is an outgoing, positive feeling without reservations and without evaluations. It means making no judgments. It involves as much feeling of acceptance for the client's expression of painful, hostile, defensive or abnormal feelings as for his expression of good, positive, mature feelings. For us as therapists, incidentally, it may be easier to accept painful and negative feelings than the positive and self confident feelings that sometimes come through. These latter we almost automatically regard as defensive. But unconditional positive regard involves a willingness to share equally the patient's confidence and joy, or his depression and failure. It is an unpossessive caring for the client as a separate person, which allows the client freely to have his own feelings and his own experiencing. One client describes the therapist as "fostering my possession of my own experience and that I am actually having it; thinking what I think, feeling what I feel, wanting what I want, fearing what I fear; no 'if's,' 'but's,' or 'not really's.'" This type of acceptance, I hold, can lead to a relationship that both facilitates the negagement of the client in the process of therapy and leads to constructive personality change.

Unconditional positive regard, when communicated by the therapist, serves to provide the nonthreatening context in which the client can explore and experience the most deeply shrouded elements of his inner self. The therapist is neither paternalistic, nor sentimental, nor superficially social and agreeable. But his deep caring is a necessary ingredient of the "safe" context in which the client can come to explore himself and share deeply with another human being.

(short part omitted).



### *Accurate Empathetic Understanding.*

The ability of the therapist to perceive experiences and feelings accurately and sensitively, and to understand their meaning to the client during the moment-to-moment encounter of psychotherapy, constitutes what can perhaps be described as the "work" of the therapist after he has first provided the contextual base for the relationship by his self-congruence or genuineness and his unconditional positive regard. Accurate empathic understanding means that the therapist is completely at home in the universe of the client. It is a moment-to-moment sensitivity in the here and now, in the immediate present. It is a sensing of the client's inner world of private personal meanings as if it were your own, while never forgetting that it is not yours. Accurate sensitivity to the client's being is of primary value during the moment-to-moment encounter of therapy; it is of limited use to the individual if the therapist only arrives at this insightful and empathic understanding of the client's experience after the interview. Such a delayed insight may be of value if the therapist has a further chance to respond to the same theme, but its value would be in formulating the moment-to-moment response to the client's immediate living of this later relationship.

The ability and sensitivity required to communicate these inner meanings again to the client in a way that allows them to be "his" experiences are the other major part of accurate empathic understanding. To sense the client's fear, his confusion, his anger, or his rage as if it were a feeling you might have (but which you are not currently having) is the essence of the perspective aspect of accurate empathy. To communicate this perception in a language attuned to the client, which allows him to more clearly formulate and sense his fear, confusion, rage, or anger, is the essence of the communicative aspect of accurate empathy,

An accurate empathic grasp of the client's conflicts and problems perhaps contrasts most sharply with the more usual diagnostic formulation of the client's experiences. This diagnostic understanding which is so different but so common, involves the implication, "I understand what is wrong with you." or "I understand the dynamics that make you act this way." Such evaluative understandings are external and sometimes even impersonal. Although they may at times be very useful in developing and understanding of the self as an *object*, they are in sharp contrast to an accurate and sensitive grasp of the personal meanings and perceptions that form the client's private world. External and evaluative understanding tends to focus the client's being on himself as object or upon intellectualizations that remove him from an ongoing contact with the experiencing going on within him. Empathic understanding when it is accurately and sensitively communicated, seems crucially important in enabling the client more freely to experience his inward feelings, perceptions and personal meanings. When he is thus in contact with his inward experiencing, he can recognize the points at which his experience is at variance with his concept of himself and, consequently, where he is endeavouring to live by a false conception. Such recognition of incongruence is the first step towards its resolution and the revision of the concept of self to include the hitherto denied experiences. This is one of the major ways in which change becomes possible and a more complete integration of self and behavior is inaugurated."

The focus on these conditions by the therapist allows for the totality of the other person to be accepted and understood. At its best this is a kind of spiritual healing with the therapist allowing herself to be a vehicle for healing energies to pass through her. It is thus not surprising that Jupp has found that congruence and empathy are strongly present in persons in an altered states of consciousness.<sup>3</sup>

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<sup>3</sup> Jupp A.C. 1976 Parapsychology and the Counsellor. Unpublished dissertation (Diploma of Advanced Study of Education) University of Keele.



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